Non-interventional study report

Study ID: NN304-4016

An international non-interventional prospective cohort study to evaluate the safety of treatment with Levemir® (insulin detemir) in pregnant women with diabetes mellitus

Diabetes Pregnancy Registry

Title page

Title	An international non-interventional prospective cohort study to evaluate the safety of treatment with Levemir® (insulin detemir) in pregnant women with diabetes mellitus
Version identifier of the final study report	1.0
Date of last version of the final study report	17 August 2020
EU PAS Register number	ENCEPP/SDPP/4137 (EUPAS4137)
EU PAS Register link	http://www.encepp.eu/encepp/viewResource.htm?id=4138
Active substance	ATC code: A10AE05; active substance: insulin detemir
Medicinal product(s)	Levemir® (insulin detemir)
Product reference	EMEA/H/C/000528
Procedure number	EMEA/H/C/000528/MEA045
Marketing authorisation holder(s)	Novo Nordisk A/S Novo Allé DK-2880 Bagsvaerd Denmark
Joint PASS	No
Research question and objectives	The overall objective of this study was to monitor and assess the safety of insulin detemir use in pregnant women with diabetes mellitus, and to monitor their infants at 1 month and at 1 year of age. **Primary objective(s):** ***Pregnancy outcome*** Comparison of the proportion of pregnancies in pregnant women who have completed 22 weeks of pregnancy and treated with insulin detemir to pregnant women who have completed 22 weeks of pregnancy and treated with other basal insulin regimens which results in none of the following events: • Major congenital malformations • Perinatal death • Neonatal death Assessed at up to 4 weeks after delivery

	Secondary objective ***Maternal*** Comparison of the following adverse events and abnormal metabolic control in pregnant women treated with insulin detemir to pregnant women treated with other basal insulin regimens: • Incidence of major hypoglycaemic events during the pregnancy period • Development of pre-eclampsia during pregnancy • Metabolic control measured as HbA_{1c} during pregnancy ***Pregnancy outcome*** Comparison of pregnancy outcomes in women treated with insulin detemir to those treated with other basal insulin regimens with respect to: • Foetal macrosomia • Large-for gestational age • Pre-term delivery • Spontaneous abortion • Induced abortion due to major congenital malformations (by organ) • Perinatal death • Neonatal death • Live birth with major congenital malformations (by organ) • Live birth with minor congenital malformations (by organ) ***Infants at the age of 1 year*** Comparison of, at 1 year of age, the growth and health of infants born to women treated with insulin detemir to those born to women treated with other basal insulin regimens.
Countries of study	This study was conducted in Croatia, Denmark, Finland, France, Germany, Greece, Ireland, Israel, Italy, Malaysia, Netherlands, Norway, Poland, Portugal, Romania, Spain and United Kingdom
Author	[redacted]
UTN	U1111-1132-9442

ClinicalTrials.gov identifier	NCT01892319
IND number	Not applicable
Generic name	Insulin detemir
Indication	Diabetes mellitus
Physician(s)	There were 17 principal investigators in the study. The signatory investigator for this report is: [redacted]
Study site(s)	The patients were enrolled at 92 sites in 17 countries (15 countries in Europe and 2 countries outside Europe):
Study initiated	30 September 2013
Study completed	30 September 2019

Marketing authorisation holder(s)

Marketing authorisation holder(s) (MAH(s))	Novo Nordisk A/S Novo Allé DK-2880 Bagsvaerd Denmark
MAH contact person	[redacted] Novo Nordisk A/S, Denmark [redacted]

This study was conducted in accordance with the Guidelines for Good Pharmacoepidemiology Practices[1], Good Pharmacovigilance Practices and the Declaration of Helsinki.[2]

Table of contents for the individual non-interventional study report

Page

Title page 2
Marketing authorisation holder(s) 4
Table of contents for the individual non-interventional study report 5
1 Abstract 12
2 List of abbreviations and definitions of terms 13
3 Other responsible parties 14
4 Physicians 15
5 Milestones 16
6 Rationale and background 17
7 Research question and objectives 21
8 Amendments and updates 23
9 Research methods 25
9.1 Study design 25
9.2 Endpoints 27
9.2.1 Primary endpoints 27
9.2.2 Secondary endpoints 27
9.2.2.1 Secondary effectiveness endpoint 27
9.2.2.2 Secondary safety endpoints 28
9.3 Setting 29
9.4 Patients 29
9.4.1 Inclusion criteria 29
9.4.2 Exclusion criteria 30
9.4.3 Removal of patients from therapy or assessment 30
9.4.4 Sources of patients 30
9.4.5 Methods of selection of patients 30
9.5 Variables 30
9.5.1 Subject disposition 30
9.5.2 Maternal baseline characteristics and demographics 31
9.5.3 Foetus, infant and delivery characteristics 33
9.5.4 Dosage of study product 35
9.5.5 Concomitant medications 35
9.6 Data sources and measurement 36
9.7 Bias 36
9.8 Study size 37
9.8.1 Sample size calculation 37
9.8.2 Original sample size calculation 37
9.8.3 Revised sample size calculation 38
9.9 Data transformation 39
9.10 Statistical methods 40
9.10.1 Analysis sets 40
9.10.2 Main statistical methods 42
9.10.3 Missing values 43
9.10.4 Sensitivity analyses 43
9.10.5 Amendments to the statistical analysis plan 43
9.11 Quality control 43
10 Results 46

10.1 Participants 46
10.2 Descriptive data 49
10.2.1 Demographic and socioeconomic information 49
10.2.2 Obstetric history 49
10.2.3 Medical history 49
10.2.4 Diabetes history 50
10.2.5 Current pregnancy 50
10.2.6 HbA1c, anthropometric measurements and vital signs at enrolment 50
10.2.7 Classes of anti-diabetic treatment at enrolment 50
10.2.8 Foetus, infant and delivery characteristics 65
10.2.9 Dosage of study product 65
10.2.10 Concomitant medications 65
10.3 Outcome data 69
10.4 Main results 69
10.4.1 Primary endpoint: proportion of pregnancies that did not result in major congenital malformations or perinatal death or neonatal death 69
10.4.2 Secondary endpoints 72
10.4.2.1 Maternal effectiveness endpoints 72
10.4.2.2 Maternal safety endpoints 73
10.4.2.3 Infant safety endpoints 89
10.4.3 Summary of main results 94
10.5 Other analyses 94
10.6 Adverse events/adverse drug reactions 94
10.6.1 Adverse drug reactions by SOC and PT 94
10.6.2 Deaths 101
10.6.3 Other serious adverse events/adverse drug reactions 101
10.6.4 Other significant adverse events/adverse drug reactions 102
10.6.5 Other observations related to safety 102
10.6.6 Pregnancy 102
10.6.7 Summary of adverse events/adverse drug reactions 102
11 Discussion 103
11.1 Key results 103
11.2 Strengths and Limitations 103
11.3 Interpretation 104
11.4 Generalisability 104
12 Other information 105
13 Conclusion 106
14 Tables, figures and listings referred to in the text 107
14.1 Demographics and other assessments 107
14.1.1 Invitation and participation - country - Enrolment log 107
14.1.2 Subject disposition - excluded - country wise – ALL analysis set 108
14.1.3 Subject disposition - discontinued and completed - country wise – FAS_MOTHER analysis set 109
14.1.4 Subject disposition - discontinued and completed - country wise – MOTHER analysis set 110
14.1.5 Subject disposition - discontinued and completed - by basal insulin treatment group at enrolment – FAS_MOTHER analysis set 111
14.1.6 Subject disposition - discontinued and completed – by basal insulin treatment group at enrolment– MOTHER analysis set 112

14.1.7 Subject disposition – participation more than once – FAS_MOTHER analysis set 113
14.1.8 Subject disposition – participation more than once – MOTHER analysis set..... 114
14.1.9 Subject disposition – participation more than once – by treatment at enrolment - FAS_MOTHER analysis set 115
14.1.10 Subject disposition – participation more than once – by treatment at enrolment - MOTHER analysis set 115
14.1.11 Subject disposition – visits – FAS_MOTHER analysis set..... 116
14.1.12 Subject disposition – visits – MOTHER analysis set 117
14.1.13 Subject disposition – visits – basal insulin treatment group at enrolment - FAS_MOTHER analysis set 118
14.1.14 Subject disposition – visits – basal insulin treatment group at enrolment - MOTHER analysis set 118
14.1.15 Subject disposition – basal insulin treatment group at enrolment - number of records – ALL analysis set 119
14.1.16 Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER..... 120
14.1.17 Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER 133
14.1.18 Foetus characteristics - basal insulin treatment group at enrolment - summary – FAS_FOETUS 146
14.1.19 Foetus characteristics - basal insulin treatment group at enrolment - summary – FOETUS 147
14.1.20 Foetus characteristics – basal insulin treatment group at enrolment - summary – FAS_LIVEBORN 148
14.1.21 Foetus characteristics - basal insulin treatment group at enrolment - summary – LIVEBORN 153
14.1.22 Infant characteristics - basal insulin treatment group at enrolment - summary – FAS_INFANT 158
14.1.23 Infant characteristics - basal insulin treatment group at enrolment - summary – INFANT 160
14.1.24 HbA1c, hypoglycaemia, and pre-eclampsia during pregnancy – summary – FAS_MOTHER analysis set 162
14.1.25 HbA1c, hypoglycaemia, and pre-eclampsia during pregnancy – summary – MOTHER analysis set 164
14.1.26 Observed insulin dose during pregnancy - basal insulin treatment group at enrolment – summary – FAS_MOTHER 165
14.1.27 Observed insulin dose during pregnancy stratified by basal insulin treatment group at enrolment – summary – MOTHER..... 168
14.1.28 Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER 170
14.1.29 Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER 207
14.1.30 Medication use by the foetus/infant at any time during the study - summary – FAS_FOETUS 237
14.1.31 Medication use by the foetus/infant at any time during the study - summary – FOETUS 243
14.1.32 Pregnancy outcomes not resulting in major malformations, perinatal death or neonatal death among foetus of women treated with basal insulin detemir compared to other basal insulins - summary – Primary analysis set 248

14.1.33 Baseline characteristics by basal insulin treatment group at enrolment before propensity score matching - PRIMARY analysis set 249
14.1.34 Baseline characteristics by basal insulin treatment group at enrolment after propensity score matching - PRIMARY analysis set 252
14.1.35 Observed HbA1c (%) during pregnancy in women treated with basal insulin detemir compared to other basal insulin – Summary – secondary effectiveness endpoint – MOTHER analysis set 255
14.1.36 Estimated mean HbA1c (%) during pregnancy in women treated with basal insulin detemir compared to other basal insulin – statistical analysis – secondary effectiveness endpoint – MOTHER analysis set 259
14.1.37 Hypoglycaemia during pregnancy in mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint – MOTHER analysis set 263
14.1.38 Pre-eclampsia during pregnancy in mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - MOTHER analysis set 264
14.1.39 Perinatal death among foetus of mothers treated with basal insulin detemir compared to other basal insulins – statistical an alysis - secondary safety endpoint - FOETUS analysis set 265
14.1.40 Neonatal death among foetus of mothers treated with basal insulin detemir compared to other basal insulins – statistical ana lysis - secondary safety endpoint - FOETUS analysis set 266
14.1.41 Induced abortion due to major malformation among foetus of mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - FOETUS analysis set 267
14.1.42 Spontaneous abortion among foetus of mothers treated with basal insulin detemir compared to other basal insulins – statistic al analysis - secondary safety endpoint - FOETUS analysis set 272
14.1.43 Major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set 273
14.1.44 Minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set 280
14.1.45 Foetal macrosomia among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins - LIVEBORN analysis set 288
14.1.46 Large for gestational age among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set 289
14.1.47 Pre-term delivery among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins - LIVEBORN analysis set 290
14.1.48 Diabetes at 1 year of age among infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - INFANT analysis set 291
14.1.49 Height and weight at 1 year of age among infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - INFANT analysis set 292
14.1.50 SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER 294

14.1.51 SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants – FAS_FOETUS 316
14.1.52 ADR categorised by System Organ Class and Preferred Term among mothers– FAS_MOTHER 342
14.1.53 ADR categorised by System Organ Class and Preferred Term among foetus/infants – FAS_FOETUS 346
14.1.54 Changes of major congenital malformations by basal insulin treatment group at enrolment before and after propensity score matching - summary - INFANT analysis set. 348
14.1.55 SAE - basal insulin treatment group at enrolment - summary – FAS_MOTHER - FAS_FOETUS 348
14.1.56 ADR - basal insulin treatment group at enrolment - summary – FAS_MOTHER - FAS_FOETUS 349
14.1.57 Subject discontinuation by delivery status - FAS MOTHER set 350
14.2 Efficacy data 351
14.2.1 Observed HbA1c during pregnancy by basal insulin treatment group at enrolment - plot (Mean +- SD) - MOTHER analysis set 351
14.2.2 Estimated HbA1c during pregnancy by basal insulin treatment group at enrolment - crude - plot - MOTHER analysis set..... 352
14.2.3 Estimated HbA1c during pregnancy by basal insulin treatment group at enrolment - adjusted plot - MOTHER analysis set..... 353
14.2.4 Odds ratio of secondary endpoints among mothers/ foetus of mothers/ liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – forest plot 354
14.2.5 Risk difference of secondary endpoints among mothers/ foetus of mothers/ liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – forest plot..... 355
14.2.6 Odds ratio of major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ - forest plot – LIVEBORN 356
14.2.7 Risk difference of major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ -forest plot – LIVEBORN..... 357
14.2.8 Odds ratio of minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ - forest plot – LIVEBORN 358
14.2.9 Risk difference of minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ -forest plot – LIVEBORN..... 359
14.2.10 Odds ratio of induced abortion due to major malformations among foetus of mothers treated with basal insulin detemir compared to other basal insulins – forest plot – FOETUS analysis set 360
14.2.11 Risk difference of induced abortion among foetus of mothers treated with basal insulin detemir compared to other basal insulins – forest plot – FOETUS analysis set 361
14.3 Safety data..... 362
14.3.3 Narratives of deaths, other serious and selected significant adverse events..... 362
15 References 8461
Appendices 8463
Annex 1. List of stand-alone documents..... 8464
Annex 2. Additional information 8465

List of in-text figures

Page

Figure 1 Sample size distribution 38
Figure 2 Total sample size sufficient to detect a minimal clinically relevant difference of 3.5% for proportion of pregnancies without the combined pregnancy outcome ranging from 92-96% (assuming a 1:1 split between the Levemir® group and the other basal insulin regimens group) 39
Figure 3 Definition of analysis sets 42
Figure 4 Risk difference of major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ -forest plot – LIVEBORN 79
Figure 5 Odds ratio of major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ - forest plot – LIVEBORN 80
Figure 6 Risk difference of minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ - forest plot – LIVEBORN 82
Figure 7 Odds ratio of minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ - forest plot – LIVEBORN 83
Figure 8 Risk difference of induced abortion among foetus of mothers treated with basal insulin detemir compared to other basal insulins – forest plot – FOETUS analysis set 85
Figure 9 Odds ratio of induced abortion due to major malformations among foetus of mothers treated with basal insulin detemir compared to other basal insulins – forest plot – FOETUS analysis set 86

List of in-text tables

Page

Table 5-1 Milestones 16
Table 8-1 Amendments to the protocol 23
Table 9-1 Flow chart of visits and standard routine procedures 26
Table 9-2 Summary of important protocol deviations at site and subject level 45
Table 10-1 Subject invitation and participation - country - Enrolment log 47
Table 10-2 Subject disposition - discontinued and completed - country wise – FAS_MOTHER analysis set 48
Table 10-3 Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER 52
Table 10-4 Pregnancy outcomes not resulting in major malformations, perinatal death or neonatal death among foetus of women treated with basal insulin detemir compared to other basal insulins - summary – Primary analysis set 71
Table 10-5 Hypoglycaemia during pregnancy in mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint – MOTHER analysis set 74
Table 10-6 Pre-eclampsia during pregnancy in mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - MOTHER analysis set 76
Table 10-7 Height and weight at 1 year of age among infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - INFANT analysis set 90
Table 10-8 Diabetes at 1 year of age among infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - INFANT analysis set 92
Table 10-9 Changes of major congenital malformations by basal insulin treatment group at enrolment before and after propensity score matching - summary - INFANT analysis set 93
Table 10-10 ADR categorised by System Organ Class and Preferred Term among mothers– FAS_MOTHER 95
Table 10-11 ADR categorised by System Organ Class and Preferred Term among foetus/infants – FAS_FOETUS 99

1 Abstract

Please refer to separate document

2 List of abbreviations and definitions of terms

ADRs	adverse drug reactions
AE	adverse event
ATC	Anatomical Therapeutic Chemical
BMI	body mass index
CGM	continuous glucose monitoring
CI	confidence interval
CRF	case report form
DBL	data base lock
DM	diabetes mellitus
eCRF	electronic case report form
EDC	electronic data capture
EMA	European Medicines Agency
EOT	end of text
EU	European Union
EU PAS	The EU electronic register of post-authorisation studies maintained by the European Medicines Agency
FPFV	first patient first visit
GLP-1 RA	GLP-1 receptor agonist
GPP	Guidelines for Good Pharmacoepidemiology Practices
GVP	Good Pharmacovigilance Practise
GW	gestation week
IEC	independent ethics committee
IRB	institutional review board
LAR	legally acceptable representative
LPLV	last patient last visit
MedDRA	Medical Dictionary for Regulatory Activities
NSR	non-interventional study report
OAD	oral antidiabetic
OR	odds ratio
PASS	Post Authorisation Safety Study
PDs	protocol deviations
PT	preferred term
RD	risk difference
SAE	serious adverse event
SAP	statistical analysis plan
SD	standard deviation
SOC	system organ class
T1DM	type-1 diabetes mellitus
T2DM	type-2 diabetes mellitus

3 Other responsible parties

Novo Nordisk was the Sponsor for this study. [redacted] was delegated by the Sponsor to support the eCRF.

4 Physicians

The list of participating sites and principal physicians is available in Appendix 16.1.4.

5 Milestones

Table 5-1 Milestones

Milestone	Planned date	Actual date
Registration in the EU PAS Register	05 July 2013	05 July 2013
Start of data collection (FPFV).	30 September 2013	30 September 2013
End of data collection (LPLV).	30 September 2019	30 September 2019
Final report of study results	20 August 2020	20 August 2020

6 Rationale and background

Background

The use of insulin analogues has increased significantly in the treatment of both type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM). Insulin analogues are used in pregnant women with diabetes, as this group has a requirement for the safe and efficacious treatment that insulin analogues can deliver. As pregnancy in women with DM is associated with an increased risk of complications for both the mother and the foetus/new-born especially if glycaemic control is outside the target, and as the treatment needs to be adjusted during pregnancy, it is considered a medical challenge to ensure that these women receive the most optimal glycaemic control without inducing hypoglycaemia. If pregnant women receive optimal treatment, it will increase both their own well-being and reduce the overall risk of diabetes complications and pregnancy complications both for the mother and the child. Complications most frequently associated with pregnancies in women with DM include the following[3-11]:

- Major hypoglycaemia
- Progression of maternal late diabetic complications
- Spontaneous abortion
- Pre-eclampsia and pre-term delivery
- Perinatal and neonatal death
- Congenital malformations
- Foetal macrosomia

During recent decades, pregnancy outcomes in women with DM have improved considerably. Hypo- and hyperglycaemia remain, however, a major challenge in the treatment of pregnant women with DM. The proportion of pregnant women reporting major hypoglycaemic episodes that require third party help is as high as 71%.[6, 8] Of these, 33−41% of the episodes additionally require parenteral glucose or glucagon.

The rate of pre-eclampsia in pregnancies in women with DM increases with advanced maternal age, poor glycaemic control and baseline proteinuria. The literature is inconsistent in particular with respect to the rate and severity of pre-eclampsia, but the minimum risk reported in women with DM is 10%.[12]

The most common organs affected by malformations are the central nervous system, heart, skeleton, kidneys, gastro-intestinal tract and lungs. The prevalence of major congenital anomalies in infants of women with DM was 4.5% in a population-based study in England, Wales and Northern Ireland [13] and the results are in line with results from a nationwide prospective Norwegian study from 2010.[14] In addition, infants of women with DM are 5 times more likely to be stillborn and 3 times more likely to die in their first month of life (neonatal death) compared with those of mothers without DM.[13] The perinatal death risk is approximately 3% and the neonatal death risk is 0.9% [13]

and comparable with rates from other European countries.[13, 15-19] Finally, foetal macrosomia is reported to occur in 25−30% and in some studies in more than 40% of the new-borns to mothers with DM.[7, 9]

Pregnant women with DM in good metabolic control are not more likely than non-diabetic women to lose a pregnancy. This is in contrast to a risk of 15−26% of having a spontaneous abortion in the first trimester for diabetic women who have elevated blood glucose levels.[5, 10, 11] As increased perinatal and neonatal death, morbidity and a 2−5-fold increase in congenital anomalies compared with the general population are reported in pregnant women with DM,[4] further data on the effects of treatment on pregnant women with DM are needed.

Rationale for the study

As prospective data on the effects of different insulin treatment regimens in general are limited and as no long-term prospective epidemiological studies examining safety in pregnant women with DM and pregnancy outcomes have been conducted, a diabetes pregnancy registry including such prospective data was highly warranted.

Novo Nordisk A/S established an international Diabetes Pregnancy Registry to monitor the safety of the use of insulin detemir and other injectable antidiabetic treatment regimens in pregnant women during the gestational period and to monitor their infants at the age of 1 month and 1 year after delivery. The present registry constituted a unique opportunity for large-scale data collection that allowed comparisons and analysis between the various insulin treatment regimens in pregnant women with DM.

All data collection and statistical analysis was done in accordance with global and local regulations and legal data protections requirements.

Rationale for study design

The Diabetes Pregnancy Registry was specifically designed to monitor and assess the safety of the use of insulin detemir in pregnant women and the health status of their infants until 1 year of age. Every diabetic woman treated with insulin or other injectable antidiabetic treatment regimens and who had not changed basal insulin or other injectable antidiabetic treatment product (for those not treated with basal insulin) 4 weeks prior to and following conception was eligible for enrolment.

The Diabetes Pregnancy Registry was based on prospectively collected clinical data as part of the normal clinical practice in pregnancy. The database was established as part of present standard clinical practice used in the treatment of pregnant women with DM at the selected study sites. A panel of the study sites enrolled in the Novo Nordisk Levemir® pregnancy trial (NN304-1687) were contacted prior to inclusion in the registry and asked to fill out a flow chart illustrating the specific standard routine procedures at their specific clinic. The standard routine procedures used with regard to the treatment of diabetic women during pregnancy were almost similar between the

included study sites resulting in a uniform treatment procedure and furthermore, these study sites had a relatively high prescription rate of Levemir®.

The prospective non-interventional study design in a large-scale setting was needed to ensure a sufficient number of patients in order to have an adequately powered study to analyse the safety of Levemir® with regard to the primary and secondary endpoints in a real-world population of pregnant women with diabetes and their infants. The collected data constituted the Diabetes Pregnancy Registry data set.

Rationale for study population

The Diabetes Pregnancy Registry was a non-interventional epidemiological study where data was collected on standard routine procedures. The results and observations from the registry would be, more broadly applicable to the real-world population of pregnant women with DM, and their infants than study populations enrolled in a typical randomised controlled trial.

Only women with either T1DM or T2DM who were treated with insulin detemir or other injectable antidiabetic treatment regimens and who had not changed basal insulin or other injectable antidiabetic product (for those not treated with insulin) 4 weeks prior to and following conception were included.

Ethics

The study was conducted in accordance with Good Pharmacoepidemiology Practice (GPP) [1], Good Pharmacovigilance Practise (GVP) Module VIII[20] and with the Declaration of Helsinki.[2]

A list of the IECs/IRBs that reviewed and approved the protocol, including approval dates is in an Appendix 16.1.3.

Informed consent form for study patients

Informed consent form was obtained from all study participants. In obtaining and documenting informed consent, the physician complied with the applicable regulatory requirement(s) and adhered to the requirements in the Declaration of Helsinki.[2]

Prior to any study-related activity, the physician gave the patient and/or the patient's legally acceptable representative (LAR) oral and written information about the study in a form that the patient or the patient's LAR could read and understand.

The requirement for using a patient's LAR was that the patient was unable to provide informed consent (e.g. was under age) and the process was approved by the relevant IRB/IEC.

A voluntary, signed and personally dated, informed consent form was obtained from the patient and/or the patient's LAR prior to any study-related activity.

The task of seeking informed consent was performed only by the physician or another medically qualified person delegated by the physician, if permitted by local regulation, who must sign and date the patient information/informed consent form.

If information became available that was relevant to the patient's willingness to continue participating in the study, the physician informed the patient and/or the patient's LAR in a timely manner and a revised written informed consent was obtained.

Premature termination of the study

The sponsor or a pertinent regulatory authority could decide to stop the study or part of the study at any time, but agreement on procedures followed was obtained. An unplanned termination of the study could occur if any serious safety issue arose with the use of insulin detemir in the pregnant women was assessed from the annual study reports.

If the study was prematurely terminated or suspended, the physician and/or sponsor had to promptly inform the IEC/IRB and provide a detailed written explanation. The pertinent regulatory authorities were informed according to national regulations.

If after the termination of the study the risk/benefit analysis has changed, the new evaluation should be provided to the IEC/IRB in case it has an impact on the planned follow-up of the patients who have participated in the study. If so, the actions needed to protect the patients should be described.

7 Research question and objectives

The overall objective of the Diabetes Pregnancy Registry was to monitor and assess the safety of insulin detemir (Levemir®) use in pregnant women with pre-existing DM, and to monitor their infants at 1 month and at 1 year of age. As part of the observational data collection, equivalent data was collected from pregnant women with DM treated with other injectable antidiabetic treatment regimens, and their infants at approximately 1 month and 1 year of age.

For the primary and secondary objectives, comparisons were made between women treated with insulin detemir and women treated with other basal insulin regimens, who have not changed basal insulin product 4 weeks prior to conception and until delivery/pregnancy termination.

Primary objective(s):

Pregnancy outcome

Comparison of the proportion of pregnancies in pregnant women who have completed 22 weeks of pregnancy and treated with insulin detemir to pregnant women who have completed 22 weeks of pregnancy and treated with other basal insulin regimens which results in none of the following events:

- Major congenital malformations
- Perinatal death
- Neonatal death

Assessed at up to 4 weeks after delivery

Secondary objective

Maternal

Comparison of the following adverse events and abnormal metabolic control in pregnant women treated with insulin detemir to pregnant women treated with other basal insulin regimens:

- Incidence of major hypoglycaemic events during the pregnancy period
- Development of pre-eclampsia during pregnancy
- Metabolic control measured as HbA_{1c} during pregnancy

Pregnancy outcome

Comparison of pregnancy outcomes in women treated with insulin detemir to those treated with other basal insulin regimens with respect to:

- Foetal macrosomia
- Large-for gestational age
- Pre-term delivery
- Spontaneous abortion
- Induced abortion due to major congenital malformations (by organ)
- Perinatal death
- Neonatal death
- Live birth with major congenital malformations (by organ)
- Live birth with minor congenital malformations (by organ)

Infants at the age of 1 year

Comparison of, at 1 year of age, the growth and health of infants born to women treated with insulin detemir to those born to women treated with other basal insulin regimens.

8 Amendments and updates

There were 6 amendments (3 global and 3 local) to the study protocol after the start of data collection in this study.

Table 8-1 Amendments to the protocol

Number	Date	Section of study protocol	Amendment or update	Reason
1*	05 December 2014	Safety assessment (section 8.2) Concomitant medications (section 8.3.4)	Change in criteria for collection of safety information Recording of concomitant medications, current insulin/anti-diabetic treatment at baseline.	Limited to adverse drug reactions and serious adverse events, as well as pre-eclampsia and major hypoglycaemic events.
2	08 October 2015	Ethics (section 15) Informed consent form for study patient (section 15.1)	Approval of protocol by an advisory committee established by the Ministry in charge of research. Physicians to obtain an oral agreement from the subject related to the use of her data in the study.	In France, non-interventional studies are not applicable for submission to/ approval by an Ethics Committee, as they are not allowed to approve observational studies in France. In France informed consent forms are not allowed for non-interventional studies as they are considered as promotional activity
3	14 January 2016	Type of study (section 5.1)	Change in inclusion criteria: patients being treated off-label not to be included into the Diabetes Pregnancy Registry or – in case a patient was already included into the Registry – was excluded from further study participation.	In Germany non-interventional studies are only allowed as long as products are used according to SmPC.
4*	11 February 2016	Inclusion and exclusion criteria (sections 6.2 and 6.3)	The exclusion criterion was changed from 12 to 16 weeks of pregnancy	To facilitate recruitment.

Number	Date	Section of study protocol	Amendment or update	Reason
5	12 June 2016	Informed consent form for study patients (section 15.1)	In France, for a minor patient included in a non-interventional study, the signature of the mother only can give the authorization of collection and analysis of data for the new-born.	Due to new analysis of the article L1122-2 II of the CSP (code of the public health).
6*	07 September 2017	Sample size calculation (section 14.1)	Sample size changed from 1833 to 1222 patients to be included in the primary analysis (i.e. 611 patients treated with insulin detemir and 611 patients treated with other basal insulin regimens)	A split of 1:1 between the number of subjects treated with insulin detemir and the number of subjects treated with other basal insulin products was observed so sample size was reduced.

*Applicable to all countries

9 Research methods

9.1 Study design

The study was a post-authorisation commitment to the European Medicines Agency (EMA) – a Post Authorisation Safety Study (PASS) – to monitor the long-term safety of insulin detemir in pregnant women to cover the gestation and lactation period.

The study was a non-interventional, multi-centre study to monitor and assess the safety of insulin detemir use during pregnancy as well as monitor the health status of the infants at 1-month and 1-year of age. The same parameters were also monitored and assessed for other injectable antidiabetic treatment regimens used during pregnancy.

The study included pregnant (gestational week ≤16 weeks at enrolment) women with type-1 diabetes mellitus (T1DM) or type-2 diabetes mellitus (T2DM) treated with insulin detemir and/or other injectable anti-diabetic treatment regimens, who had not changed injectable anti-diabetic treatment product 4 weeks prior to conception and following conception .

Patients were allowed to change treatment after enrolment, but for the main analyses of the primary and secondary objectives, only women treated with basal insulin, who had not changed basal insulin product 4 weeks prior to conception and until delivery/pregnancy termination were included. The group of women treated with insulin detemir was compared to the group of women treated with other basal insulins.

Please refer to the protocol (Appendix 16.1.1, Section 8.1) and SAP (Appendix 16.1.7) for more details on the visits. Visits and data collections are outlined in Table 9-1.

Table 9-1 Flow chart of visits and standard routine procedures

Visit	**Baseline visit**	**Standard routine visits**	**Delivery visit**	**Follow-up of the infant(s)**	**Follow-up of the infant(s)**
Time of visit	≤ 16 weeks pregnant	Any time during pregnancy [5]	Delivery	1 month after delivery	1 year after delivery
Visit window				+ 1 month	+ 4 months
Informed consent	x				
Incl. /excl. criteria	x				
Demographics	x				
Obstetric history	x				
Maternal medical history	x				
Maternal diabetes history	x				
Current antidiabetic treatment	x	x	x		
Concomitant illness	x				
Concomitant medication	x	x	x		
Height [1]	x		x	x	x
Weight [1]	x	x	x	x	x
Vital signs	x	x			
Current pregnancy information	x				
HbA_{1c}	x [2]	x	x		
Major hypoglycaemia		x	x		
Pre-eclampsia		x	x		
ADRs and SAEs [3]		x	x	x	x
Delivery and complications			x		
Pregnancy outcome			x		
Neonatal assessments			x		
Foetal assessments [4]			x		
Neonatal death				x	
Congenital malformations not detected at delivery				x	
Lactation				x	x
Diabetes					x
Changes of major congenital malformations					x

1. Height and weight of the mother during pregnancy and of the infant(s) at delivery, 1 month and 1 year follow-up

2 HbA_{1c} measured ≤ 16 weeks prior to baseline visit is acceptable as baseline visit data (see section 8.1.1 in the protocol)

3 Relevant ADR's and SAE's according to protocol section 9.

4 Foetal assessments in case of early termination of pregnancy, perinatal and neonatal death

5 Preferably data from one standard routine visit per month should be entered into the eCRF irrespectively of the number of visits performed

9.2 Endpoints

For definitions of endpoints please refer to Appendix 16.1.1

9.2.1 Primary endpoints

The primary endpoint was a composite endpoint consisting of none of the following pregnancy outcomes (Yes/No) assessed from gestational week 22 and up to 4 weeks after delivery (i.e. the 1-month visit):

- Major congenital malformations (a life-threatening structural anomaly or an abnormality likely to cause significant impairment of health or functional capacity and which needs medical or surgical treatment)
- Perinatal death (death of a foetus/infant between ≥ 22 completed gestational weeks and < 1 completed week after delivery)
- Neonatal death (death of an infant between 7 days and 28 completed days after delivery)

The primary effect measure was the simple crude risk difference (RD), (also called absolute risk reduction) between the proportions of the primary endpoint in the two primary comparisons groups.

The primary comparison groups were pregnant women treated with insulin detemir to pregnant women treated with other basal insulin regimens. Besides passing baseline inclusion/exclusion criteria, the women should have completed 22 weeks of pregnancy, and not changed basal insulin 4-weeks prior to conception and until delivery/pregnancy termination. Note, for pregnancies with multiple foetuses each foetus was counted individually. For details on definitions, analyses and presentation of primary endpoints please refer SAP (Appendix 16.1.7, Section 7.1)

9.2.2 Secondary endpoints

9.2.2.1 Secondary effectiveness endpoint

The following secondary effectiveness endpoint was compared between pregnant women treated with insulin detemir to pregnant women treated with other basal insulin regimens, who passed baseline inclusion/exclusion criteria and have not changed basal insulin 4 weeks prior to conception and until delivery/pregnancy termination:

Secondary maternal effectiveness endpoint:

- HbA_{1c} during pregnancy

For details on definitions, analyses and presentation of secondary effectiveness endpoint, please refer SAP (Appendix 16.1.7, Section 7.2)

9.2.2.2 Secondary safety endpoints

The following secondary safety endpoints were compared between pregnant women treated with insulin detemir and pregnant women treated with other basal insulin regimens, who have passed baseline inclusion/exclusion criteria and have not changed basal insulin 4 weeks prior to conception and until delivery/pregnancy termination:

Secondary maternal safety endpoints

- Major hypoglycaemia during pregnancy (hypoglycaemic episode where the patient is not able to treat herself and where oral carbohydrates, glucagon or intravenous glucose has to be administered to the patient by another person because of severe central nervous system dysfunction)
- Pre-eclampsia during pregnancy [A condition in pregnancy characterised by new onset of hypertension (140/90 millimetres of mercury (mm Hg) or greater documented on two occasions, at least 6 hours but no more than 7 days apart), and albuminuria].

Secondary pregnancy outcome safety endpoints

- Perinatal death (death of a foetus/infant between ≥ 22 completed gestational weeks and < 1 completed week after delivery)
- Neonatal death (death of an infant between 7 days and 28 completed days after delivery)
- Major congenital malformations (overall and by organ)
- Minor congenital malformations (overall and by organ)
- Induced abortions due to major congenital malformations (overall and by organ)
- Spontaneous abortion (naturally occurring termination of a pregnancy before 22 completed gestation weeks)
- Foetal macrosomia (birth weight above 4 kg)
- Large for gestational age (live born infant with birth weight > 90th percentile for gestational age and sex according to local reference)
- Pre-term delivery (delivery before completion of 37 weeks of gestation)

Secondary infant safety endpoints:

- Height at the age of 1 year
- Weight at the age of 1 year
- DM status
- Changes (progression/regression) of major congenital malformations

Safety information (women and offspring):

- Serious adverse events (SAE)
- Adverse drug reaction (ADR)

For details on definitions, analyses and presentation of secondary safety endpoint, please refer SAP (Appendix 16.1.7, Section 7.3)

9.3 Setting

This study was set to be conducted at 92 sites in 17 countries. The total number of patients to be included during the recruitment period was planned to be 2,037. Recruitment was closed once it was secured that at least 611 patients treated with insulin detemir were eligible for the primary analysis. Patients were treated according to routine clinical practice at the discretion of the treating physician. The study included patients treated with insulin detemir and/or other injectable anti-diabetic treatment regimens, who did not change injectable anti-diabetic treatment product 4-weeks prior to conception and following conception.

The following exposure variable was defined and categorised as follows:

Basal insulin treatment group at enrolment (i.e. from 4 weeks prior to conception and following conception):

- insulin detemir
- another basal insulin

No basal insulin

Descriptive statistics including number of patients with information (n), and n and % in the different exposure categories were reported for the all analysis sets.

9.4 Patients

Only women with either T1DM or T2DM who were treated with insulin detemir or other injectable antidiabetic treatment regimens and who had not changed basal insulin or other injectable antidiabetic product (for those not treated with insulin) 4 weeks prior to and following conception were included. During the pregnancy the women attended regular visits to specialist clinics for the treatment of their DM and therefore experienced clinics with a high number of potential candidates were contacted to participate in the study.

9.4.1 Inclusion criteria

For an eligible patient, all inclusion criteria were to be answered “yes”.

1. Informed consent obtained before any data collection
2. Woman with a positive pregnancy test
3. Diabetes mellitus type 1 or 2, diagnosed prior to conception
4. On treatment with Levemir® or other injectable antidiabetic treatment(s)
5. Unchanged basal insulin or other injectable antidiabetic treatment product (for those not treated with basal insulin) 4 weeks prior to and following conception

An eligible woman could be included in the Diabetes Pregnancy Registry more than once, should the pregnancies had occurred within the recruitment period.

9.4.2 Exclusion criteria

Women who were pregnant for more than 16 weeks at baseline visit were excluded from the study.

9.4.3 Removal of patients from therapy or assessment

Patients could withdraw at will at any time, for any reason.

9.4.4 Sources of patients

Women with T1DM and T2DM, who were pregnant and were treated with insulin detemir or other injectable antidiabetic treatment regimens, were invited to participate in the Diabetes Pregnancy Registry.

9.4.5 Methods of selection of patients

The sites were instructed to invite all women fulfilling inclusion criteria and not to select among potential candidates only. Patients were identified by physicians and included in the study based on inclusion criteria (see Section 9.4.1). In order to obtain as much information as possible within an appropriate timeframe, women who had a positive pregnancy test and were diagnosed with DM prior to conception, and who had not changed basal insulin or other injectable antidiabetic treatment product (for those not treated with basal insulin) 4 weeks prior to and following conception were included in the Diabetes Pregnancy Registry.

9.5 Variables

9.5.1 Subject disposition

Number of women invited, and number of women enrolled (defined as signed informed consent) were reported based on numbers retrieved from the enrolment log kept at each study site. The data was reported overall and stratified by country.

Number of women and reasons for fulfilling/not fulfilling baseline inclusion and exclusion criteria were reported using the ALL analysis set (Figure 3). These data were reported overall and stratified by country. Furthermore, number of women and reasons for discontinuing the study during follow-up, and number of women completing the study were reported for the FAS_MOTHER, and MOTHER analysis sets (please see section 9.10.1 for details of analysis sets). Discontinuation of the study was defined as withdrawal by the participant, lost to follow-up, and other reasons for discontinuation. Completion of the study was defined as completion of the 1-year infant examination, ectopic pregnancy, abortion, or death of foetus/infant. The data was reported overall and stratified by country and by basal insulin treatment group at enrolment (insulin detemir, other basal insulin, no basal insulin), respectively.

Moreover, number of times and number of women participating more than once in the study were reported for the FAS_MOTHER and MOTHER analysis sets. The data was reported overall and stratified by country and basal insulin treatment group at enrolment (insulin detemir, other basal insulin, no basal insulin), respectively.

Also, number of women attending the baseline visit, the standard routine visit(s), the delivery visit, follow-up of the infants 1-month after delivery visit, and follow-up of the infants 1-year after delivery visit was reported for the FAS_MOTHER and MOTHER analysis set. Data was reported overall and stratified by country and basal insulin treatment group at enrolment (insulin detemir, other basal insulin, no basal insulin), respectively.

Finally, number of women/foetuses/infants included in the ALL, FAS_MOTHER, FAS_FOETUS, FAS_LIVEBORN, FAS_INFANT, MOTHER, FOETUS, LIVEBORN, INFANT, and PRIMARY analysis sets were reported. Data was reported overall and stratified by basal insulin treatment group at enrolment and by country.

9.5.2 Maternal baseline characteristics and demographics

Baseline characteristics and demographics collected at enrolment were reported for the FAS_MOTHER and MOTHER analysis set. Data was reported overall and stratified by basal insulin treatment group at enrolment (insulin detemir, other basal insulin, no basal insulin). The descriptive characteristics reported included number of patients with information (n), mean, standard deviation (SD), median, 2.5% and 97.5% percentiles, minimum and maximum for continuous variables and n and % for categorical variables. The denominator for calculation of % was number of women with non-missing data for the variable in question.

The following maternal information was recorded at baseline visit:

Demographic and socioeconomic information

- Country (Croatia, Denmark, Finland, France, Germany, Greece, Ireland, Israel, Italy, Malaysia, Netherlands, Norway, Poland, Portugal, Romania, Spain, United Kingdom)
- Age (continuous)
- Race (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, White, Other)
- Education (university degree, college degree, graduate school, technical school, high school, A levels, intermediate school leaving certificate, basic school leaving certificate, primary school, no education, other)
- Occupation (managerial (employed or self-employed), professional and higher technical, clerical or lower technical, skilled worker, semiskilled worker, unskilled worker, student, not working, other)
- Tobacco (never, previous, current)
- Alcohol (Yes/No)

Obstetric history

- Number of previous pregnancies (0, 1, 2, 3, 4+)
- Number of previous live births (0, 1, 2, 3, 4+)
- Previous pre-eclampsia (Yes/No)
- Previous caesarean section (Yes/No)
- Previous perinatal deaths (Yes/No)
- Previous preterm delivery (Yes/No)
- Previous spontaneous abortion (Yes/No)
- Previous malformations (Yes/No)
- Previous minor malformations (Yes/No)
- Previous major malformations (Yes/No)

Medical history

- Hypertension (Yes/No)
- Epilepsy (Yes/No)
- Thyroid disorder (Yes/No)
- Asthma (Yes/No)
- Heart disease (Yes/No)
- Psychiatric disorder (Yes/No)
- Inheritable diseases (Yes/No)

Diabetes history:

- Type of DM (T1DM, T2DM)
- Diabetes duration (continuous; <5, ≥ 5 years)
- History of diabetes complications (Yes/No)
- History of microvascular complications (Yes/No)
- History of macrovascular complications (Yes/No)
- History of retinopathy (Yes/No)
- History of neuropathy (Yes/No)
- History of macroangiopathy (including peripheral vascular disease) (Yes/No)
- History of acute myocardial infarction (Yes/No)
- History of unstable angina (Yes/No)
- History of heart failure (Yes/No)

Current pregnancy

- Gestational age at enrolment (continuous; <7, ≥ 7 to 12, ≥ 12 to 16 weeks)
- Folic acid taken before and during first trimester (Yes/No)

HbA1c, anthropometric measurements and vital signs at enrolment

- HbA_{1c} (continuous; <7% (Yes/No); <6.5% (Yes/No); <5.5, ≥5.5 to 6.0, ≥6.0 to 6.5, ≥6.5 to 7.0, ≥7.0 to 7.5, ≥7.5 to 8.0, ≥8.0 to 8.5, ≥8.5 to 90, ≥9.0 to 9.5, ≥9.5)
- Weight (continuous)
- BMI (continuous; <18.5, ≥18.5 to 25, ≥25.0 to 30, ≥30 to 35, ≥35 to 40, ≥40 kg/m2)
- Systolic blood pressure (continuous; <130; ≥130 to 140; ≥140 mmHg)
- Diastolic blood pressure (continuous; <85; ≥85 to 90; ≥90 mmHg)
- Pulse (continuous; <60 , 60-100, >100 beats per minute)

Classes of anti-diabetic treatment at enrolment

- Basal insulin at enrolment (Yes/No)
- Bolus (short-acting) insulin at enrolment (Yes/No)
- Premix insulin at enrolment (Yes/No)
- OAD at enrolment (Yes/No)
- GLP-1 RA at enrolment (Yes/No)

9.5.3 Foetus, infant and delivery characteristics

Foetus, infant and delivery characteristics collected at the delivery and 1-month and 1-year post-partum visit were reported as described below. The descriptive statistics included number of patients with information (n), mean, standard deviation (SD), median, 2.5% and 97.5% percentiles, minimum and maximum for continuous variables and n and % for categorical variables. The denominator for calculation of % was number of women/ foetus/ infant with non-missing data for the variable in question.

The following foetus characteristics were reported for the FAS_FOETUS and FOETUS analysis set. Data was reported overall and stratified by basal insulin treatment group at enrolment (insulin detemir, other basal insulin, no basal insulin):

- Abortion (Yes/No)
- Spontaneous abortion (Yes/No)
- Induced abortion (Yes/No)
- Perinatal death (Yes/No)
- Neonatal death (Yes/No)
- Liveborn (Yes/No)

The following characteristics were reported for the FAS_LIVEBORN and LIVEBORN analysis set. Data was reported overall and stratified by basal insulin treatment group at enrolment (insulin detemir, other basal insulin, no basal insulin):

- Sex (Male/ Female)

- Head circumference (continuous)
- Birth weight (continuous)
- Length at birth (continuous)
- Apgar score at 5 minutes (continuous, 0-3; 4-6; 7-10 points)
- Admission to intensive care for more than 48 hours (Yes/No)
- Arterial umbilical cord PH (continuous)
- Birth injury (Yes/No)
- Respiratory distress syndrome (Yes/No)
- Neonatal hypoglycaemia (Yes/No)
- Gestational week at delivery (continuous, gestational week <37; gestational week ≥ 37)
- Multiple birth (Yes/No)
- Spontaneous onset of labour (Yes/No)
- Induction of labour (Yes/No)
- Vaginal delivery (Yes/No)
- Caesarean section (Yes/No, planned, non-planned, no caesarean section)
- Major congenital malformation (Yes/No)
- Minor congenital malformation (Yes/No)
- Pre-term delivery (Yes/No)
- Foetal macrosomia (Yes/No)
- Large-for gestational age (Yes/No)

The following infant characteristics were reported for the FAS_INFANT and INFANT analysis set. Data was reported overall and stratified by basal insulin treatment group at enrolment (insulin detemir, other basal insulin, no basal insulin):

- Weight at 1-month visit (continuous)
- Height at 1-month visit (continuous)
- Previous lactation (partial and/or exclusive) at 1-year visit (Yes/No)
- Height at 1-year visit (continuous)
- Weight at 1-year visit (continuous)
- DM in the infant at 1-year visit (Yes/No)
- Changes of major congenital malformations (no change, progression, regression, both progression and regression, no major congenital malformation)

The following maternal characteristics were reported for the FAS_MOTHER and MOTHER analysis set. Data was reported overall and stratified by basal insulin treatment group at enrolment (insulin detemir, other basal insulin, no basal insulin):

- HbA_{1c} at baseline visit
- HbA_{1c} at conception (GW=2)

- HbA_{1c} at end of first trimester (GW=12)
- HbA_{1c} at end of second trimester (GW=28)
- HbA_{1c} at end of third trimester (GW=40)
- HbA_{1c} at delivery
- Major hypoglycaemia during pregnancy (Yes/No)
- Pre-eclampsia during pregnancy (Yes/No)

9.5.4 Dosage of study product

Observed insulin dose (basal, bolus, premix, total; in units and units/kg) at enrolment was reported stratified by basal insulin treatment group at enrolment. Data was reported for the FAS_MOTHER and MOTHER analysis sets.

Descriptive statistics were reported including n, mean, SD, median, 2.5% and 97.5% percentiles, min, and max.

9.5.5 Concomitant medications

Glucose-lowering treatment and other concomitant medication taken by the mother at any time during pregnancy, and during specific time periods (during first trimester (GW=0-12), during second trimester (GW=13-28), during third trimester (GW=29-40+) were presented for the FAS_MOTHER and MOTHER analysis sets. Glucose-lowering treatment and other concomitant medication taken after pregnancy termination were not included. Data was reported overall and stratified by basal insulin treatment group at enrolment (insulin detemir, other basal insulin, no basal insulin).

The medication was defined and reported according to the Anatomical Therapeutic Chemical (ATC) Classification System (therapeutic subgroup (ATC level 2) and chemical subgroup (ATC level 4) for example A10 Drugs used in diabetes (level 2) and A10BA biguanides (level 4). Medications that could not be coded e.g. combinations product or medications with multiple indications were categorised in a separate category. Also, medications that could be considered dietary supplements were categorised in a separate category.

Descriptive statistics were reported including number of patients with information (n), and n and % in the different exposure categories.

Similarly, medication taken by the infants at any time during the study were reported overall and stratified by basal insulin treatment group at enrolment (insulin detemir, other basal insulin, no basal insulin) for the FAS_FOETUS and FOETUS analysis sets.

9.6 Data sources and measurement

Novo Nordisk A/S provided a system for electronic data capture and eCRFs were provided as a web-based solution. This system and support services to the system were supplied by a vendor. The activities of this vendor were under the direction and supervision of Novo Nordisk A/S.

The eCRF was ensured to be as complete as possible.

If a test/assessment had not been done and was not available, or if the question was irrelevant (e.g. was not applicable) this was indicated according to the instructions for completing eCRFs.

Corrections to the eCRF data was done only by the physician or the physician's authorised staff. An audit trail was maintained in the EDC application containing as a minimum: identification of the person entering the data, date and time of the entry and reason for the correction, the original entry and the corrected entry.

If corrections were made by the physician's authorised staff after the date of the physician's signature on the case book, the case was signed again by the physician.

The physician ensured that data was recorded in the eCRFs as soon as possible after the visit. When data was entered it was available to Novo Nordisk A/S for data verification activities.

By signing the case book electronically, the physician confirmed that the information was complete and correct.

9.7 Bias

Due to the nature of the study, the results would contribute to the current knowledge regarding treatment of pregnant women with both insulins and other injectable antidiabetic treatment regimens. A substantial high number of patients in the registry would enable confirmation of existing evidence from clinical studies and a generation of new hypotheses with respect to the long-term safety of insulin detemir and other injectable antidiabetic treatment regimens in pregnant women with DM and their infants.

A heterogeneous patient population and different local requirements with regard to the routine patient management could limit the explanatory power of the study results if not well-adjusted in the analysis part. Heterogeneity however was minimal in the present registry as the study sites have many similarities with regard to standard routine procedures in the treatment of pregnant women with DM. Confounding factors and other relevant background covariates were collected at the baseline visit in order to adjust for relevant factors in the statistical analysis.

Results from statistical analysis could be biased if not all pregnancies were registered in the Diabetes Pregnancy Registry, particularly if data was only entered when the patient experienced an ADR/SAE. In order to minimise the risk of such bias the physician ensured that all registered

pregnancies regardless of treatment regimens in the specific clinic were enrolled in the Diabetes Pregnancy Registry unless the women did not want to participate (did not sign the informed consent form).

9.8 Study size

9.8.1 Sample size calculation

The sample size calculation was based on the combined primary endpoint, which was to compare the proportion of pregnancies in pregnant women treated with insulin detemir to pregnant women treated with other basal insulin regimens which resulted in none of the 3 individual outcomes: major congenital malformations, perinatal or neonatal death.

Due to new knowledge obtained after study initiation regarding the observed split between treatment groups and pregnancy outcome incidence, a revised sample size calculation was performed that took the differences from the original assumptions into account (section 8, amendment number 6) The original and revised sample size calculations are described in Sections 9.8.2 and 9.8.3, respectively.

9.8.2 Original sample size calculation

The following proportions were assumed for each of the individual outcomes

- Major congenital malformations: 4.5%
- Perinatal death: 3%
- Neonatal death: 0.9%

The probability of the combination of the endpoints was not known in the literature but the proportion of pregnancies with any of the above outcomes were estimated at 8.2% as described below. This combined probability was computed under the assumption that the individual outcomes are independent.

The primary endpoint was the proportion of pregnancies without any of the above outcomes. The proportions of patients not getting any of the outcomes was assumed to:

- Major congenital malformations: 1-0.045=0.955
- Perinatal death: 1-0.03=0.97
- Neonatal death: 1-0.009=0.991

None of the outcomes: 0.955 x 0.97 x 0.991 = 0.918, i.e. 91.8% of patients were expected not to get any of the pregnancy outcomes above, and 100%-91.8% = 8.2% were expected to get one of the outcomes.

The sample size calculation was based on the assumption that the proportion of pregnancies without the combined pregnancy outcome was 91.8% in the insulin detemir group or the other basal insulin regimens group. The goal was to detect a difference of 3.5% between the proportions without the combined endpoint in the insulin detemir group compared to the other basal insulin regimens group. Assuming a maximum 1:2 split between the two groups, a sample size of 1,833 pregnancies was needed in order to have 80% power of achieving significance at 5% level (see Figure 1)

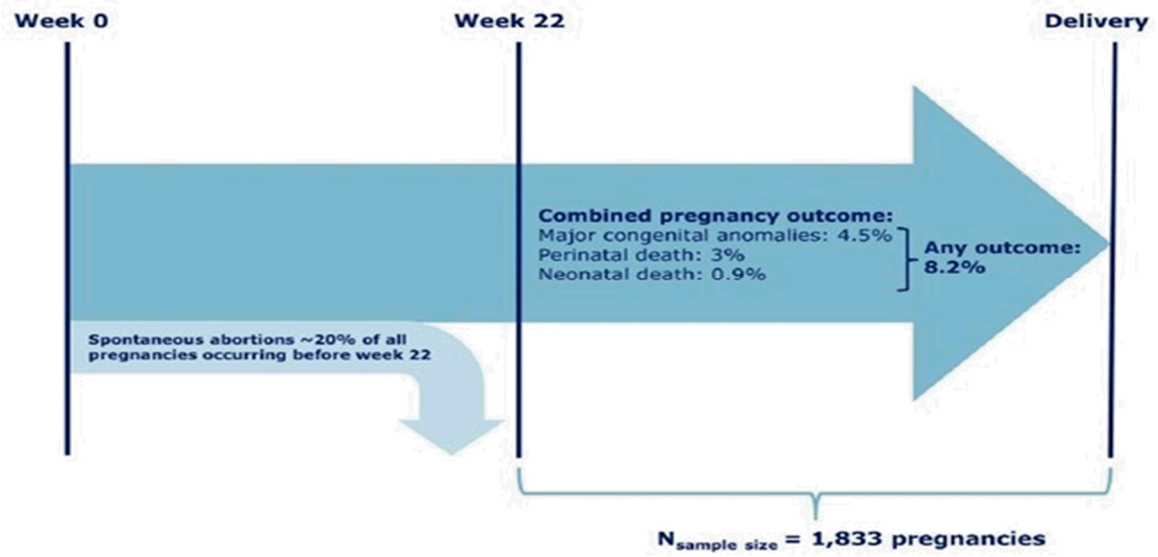

Figure 1 Sample size distribution

Thus, in total 1,833 pregnancies (including pregnancy outcome and follow-up in the infants) were needed assuming a maximum 1:2 balance between the two groups, (i.e. in the most extreme case there are 611 pregnancies in one group, and 1,222 pregnancies in the other group). With an estimated annual enrolment of 615 patients, this was possible within the 5 years enrolment period.

9.8.3 Revised sample size calculation

A revised sample size calculation was performed based on a 1:1 split between the number of subjects treated with insulin detemir and the number of subjects treated with other basal insulin products. Figure 2 shows the revised sample size calculation based on a 1:1 split between the groups and pregnancy outcome incidences ranging from 92% to 96%. As indicated in the figure, a total sample size of 1222 (based on a 1:1 split including 611 subjects treated with insulin detemir and 611 patients on other basal insulin regimens) was sufficient to detect a difference of 3.5% in the primary endpoint measure when the proportion of pregnancies resulting in none of the 3 pregnancy outcomes was ≥93.5%.

This sample size of 1222 was likely to be sufficient, even if the proportion of pregnancies resulting in none of the 3 pregnancy outcomes, unexpectedly, was lower than the currently observed (97.3% observed versus 91.8% originally assumed).

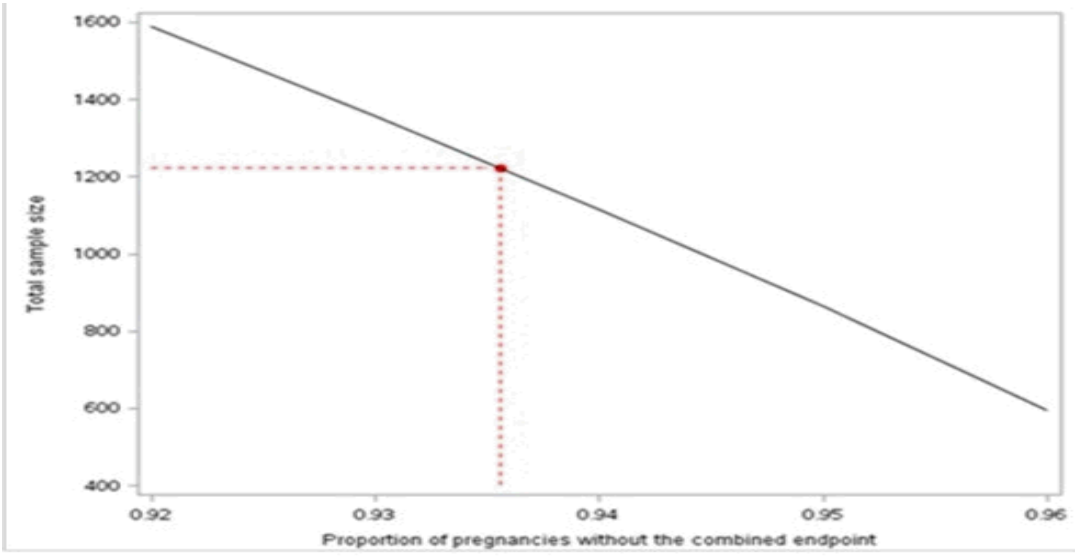

Figure 2 Total sample size sufficient to detect a minimal clinically relevant difference of 3.5% for proportion of pregnancies without the combined pregnancy outcome ranging from 92-96% (assuming a 1:1 split between the Levemir® group and the other basal insulin regimens group)

When calculating the number of subjects to be enrolled in the study, it was considered that not all subjects would qualify for the primary analysis. The percentage of enrolled subjects, which were excluded from the primary analysis was approximately 40% and thereby in line with the original assumption used for the sample size calculation. Therefore, the sample size was adjusted to 1222/ (1-0.40) =2037 (as a minimum) subjects enrolled in the study.

9.9 Data transformation

Data management was the responsibility of Data Management, Novo Nordisk A/S. [redacted] was contracted to support the eCRF system.

The physician ensured that data was recorded in the eCRFs as soon as possible after the visit. When data was entered it was available to Novo Nordisk A/S for data verification activities. Each patient and infant were identified by a patient number. The physician or qualified staff entered the data by using the electronic CRFs. Data managers, who were responsible for the Diabetes Pregnancy Registry Database, followed-up on the data flow and prepared periodical reports to be communicated to Novo Nordisk A/S and clinics participating in the registry to ensure correctness of data. Appropriate measures such as encryption or deletion were enforced to protect the identity of

human patients in all presentations and publications as required by local/regional/national requirements.

9.10 Statistical methods

9.10.1 Analysis sets

The following analysis sets were defined for this study (Figure 3).

ALL: This analysis set included all women (n=2446) who had signed informed consent before any data collected. This analysis set contained one record per woman; and was used for reporting the patient disposition of all enrolled women. Women participating in the study more than once were counted more than once.

FAS_MOTHER: This analysis set included all women (n=2373) who met all the inclusion criteria, and not the exclusion criteria. The analysis set contained one record per woman and was used for descriptive analyses. Women participating in the study more than once were counted more than once.

FAS_FOETUS: This analysis set included all foetuses (n=2396) of women included in the FAS_MOTHER analysis set. If the outcome of the pregnancy was not known the foetus was excluded from the analysis set. For pregnancies with multiple outcome each foetus/infant was counted individually, and the analysis set contained one record per foetus/infant. The analysis set was used for descriptive analyses.

FAS_LIVEBORN: This analysis set included all foetuses (n=2186) included in the FAS_FOETUS analysis set, who were alive at delivery. If vital status at delivery was dead or unknown, the foetus was excluded from the analysis set. For pregnancies with multiple outcome each foetus/infant was counted individually, and the analysis set contained one record per foetus/infant. The analysis set was used for descriptive analyses.

FAS_INFANT: This analysis set included all infants (n=2043) included in the FAS_LIVEBORN analysis set, who completed the 1-year follow-up examination. If the 1-year follow-up examination was not completed the infant was excluded from the analysis set. For pregnancies with multiple outcome each infant was counted individually, and the analysis set contained one record per infant. The analysis set was used for descriptive analyses.

MOTHER: This analysis set included all women (n=1457) included in FAS_MOTHER, who were treated with basal insulin at enrolment, and who had not changed basal insulin 4 weeks prior to conception and until delivery/pregnancy termination. In case of change in basal insulin or if change

unknown, the woman was excluded from the analysis set. The analysis set contained one record per woman and was used for analyses of secondary maternal endpoints.

FOETUS: This analysis set included foetuses (n=1481) of women included in the MOTHER analysis set. If the outcome of the pregnancy was not known the foetus was excluded from the analysis set. For pregnancies with multiple outcome each foetus was counted individually, and the analysis set contained one record per foetus. The analysis set was used for analyses of secondary pregnancy outcome endpoints.

LIVEBORN: This analysis set included all infants (n=1351) included in the FOETUS analysis set, who were alive at delivery. If vital status at delivery was dead or unknown, the infant was excluded from the analysis set. For pregnancies with multiple outcome each infant was counted individually, and the analysis set contained one record per infant. The analysis set was used for analyses of secondary infant endpoints.

INFANT: This analysis set included all infants (n=1268) included in the LIVEBORN analysis set, who completed the 1-year follow-up examination. If the 1-year follow-up examination was not completed the infant was excluded from the analysis set. For pregnancies with multiple outcome each infant was counted individually, and the analysis set contained one record per infant. The analysis set was used for analyses of secondary infant endpoints.

PRIMARY: This analysis set included all foetuses (n=1360) included in FOETUS analysis set, who completed 22 gestational weeks. If unknown, the foetus/infant was excluded from the analysis set. For pregnancies with multiple outcome each foetus/infant was counted individually, and the analysis set contained one record per foetus/infant. This analysis set was used for the analysis of the primary endpoint.

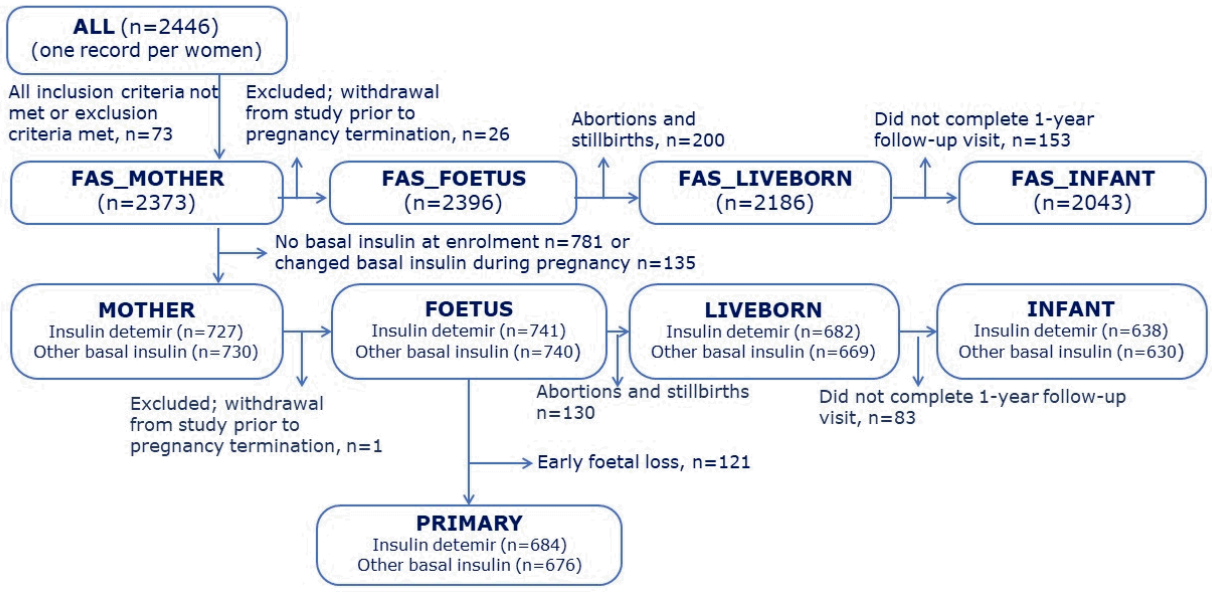

Figure 3 Definition of analysis sets

9.10.2 Main statistical methods

All statistical tests were performed as two-sided tests with a significance level of 0.05.

All statistical analyses were performed for all countries combined unless otherwise stated.

In general, the statistical analyses were complete case analysis i.e. patients were excluded from respective analyses in case of missing information on required variables. Also, it was assumed that observations were independent of each other.

For all primary and secondary endpoints both crude and confounder adjusted analyses were performed. The crude analysis did not take into account confounding due to differences between the two treatment groups. Potential confounding was adjusted for by propensity score matching (binary endpoints) or multiple regression analysis (continuous endpoints). The descriptive statistics is described in sections 9.5.2 and 9.5.3.

The primary endpoint, proportion of pregnancies not resulting in major congenital malformation, perinatal or neonatal death were computed for the insulin detemir group, and for the other basal insulin group. The primary analysis of the primary endpoint was the crude risk difference between these proportions. Furthermore, the odds ratios were calculated. Estimates were reported along with the 95% confidence interval and the p-value. These analyses were performed for all binary

endpoints. Continuous endpoints were evaluated in linear regressions models. For all endpoints both crude and confounder adjusted analyses were performed. Potential confounding was adjusted for by propensity score matching (binary endpoints) and multiple regression (continuous endpoints).

For the analysis of HbA_{1c} during pregnancy, available HbA_{1c} measurements from 16 weeks prior to conception and until pregnancy termination were assigned to either "conception" (GW=2), "end of first trimester" (GW=12), "end of second trimester" (GW=28) or "end of third trimester" (GW=40) based on the actual date of the HbA_{1c} measurements, and which of these time points it was closest to.

All statistical analyses were performed using SAS-7.1 statistical software. All statistical tests were performed as two-sided tests with a significance level of 0.05.

9.10.3 Missing values

Missing data entries were identified through automated checks and thorough data review prior to database lock and queried. However, it was not expected to have complete data from all participants thus statistical analyses were based on patients with available information for the respective analyses. Number of patients included in the individual analyses were reported.

9.10.4 Sensitivity analyses

No sensitivity analyses were performed.

9.10.5 Amendments to the statistical analysis plan

The following are changes to the statistical analyses that were described in the protocol:

For binary endpoints propensity score matching was used to adjust for potential confounding, as the logistic regression analyses including a large number of covariates as described in the protocol were likely not feasible due to the low number of cases with adverse pregnancy outcomes. The list of potential confounders was revised, and mediators and other variables not expected to confound the associations of interest were removed. Please refer to SAP for details.

9.11 Quality control

The study was conducted in accordance with Good Pharmacoepidemiology Practice (GPP)[1], Good Pharmacovigilance Practise (GVP) Module VIII[20] and with the Declaration of Helsinki.[2]

During the course of the study, the supervisor visited the study site to ensure that the protocol had been adhered to and that all issues and data were recorded. The supervisor ensured that the eCRFs were completed.

Patient data was entered to the Diabetes Pregnancy Registry Database without any personal identifying data such as names and social security numbers. Patients were only identifiable by their

physician via the unique Diabetes Pregnancy Registry Patient ID and their date of birth. All data in the Diabetes Pregnancy Registry Database was anonymous.

Protocol deviations

Protocol deviations (PDs) were reviewed and classified as important or not important by the study group prior to database lock (DBL). Protocol deviations were recorded at study sites according to a set of pre-specified categories. The site monitors assigned each PD to a category. The detailed listings in Appendix 16.2.2 reflect the protocol deviation categories as they were reported. A total of 838 important PDs were reported in this study; all of which were closed before DBL on 25 November 2019. None of the important PDs were considered to have an overall impact on the trial conduct, subject safety, or data interpretation.

Summary of important protocol deviations

Assessment deviations

There were 17 subject-level PDs in the 'assessment deviations' category. All PDs in this category were due to late reporting of SAEs.

Inclusion/exclusion/randomisation criteria

There were 5 site-level PD and 171 subject-level PDs in the 'inclusion/exclusion/randomisation criteria' category. Most of the subject level PDs were due to enrolment of patients despite the inclusion criteria 5 was not met.

Informed consent

There were 12 site-level PDs and 260 subject-level PDs in the 'informed consent' category. Most of the subject level PDs were due to wrong information in informed consent form version 5 or wrong ICF process.

Other deviations

There were 15 site-level PDs and 358 subject-level PDs in the 'other' category.

Important protocol deviations at site level

There were 32 important PDs reported at the site level (Table 9-2).

Important protocol deviations at subject level

There were 806 important PDs reported at the subject level (Table 9-2).

Full description of the site-level and subject-level PDs are provided in Appendix 16.2.2 as follows:

Listing 16.2.2.1 – Protocol deviations - site and subject level - by category
Listing 16.2.2.2 – Protocol deviations - site and subject level - by category and title
Listing 16.2.2.3 – Protocol deviations - site level - by category
Listing 16.2.2.4 – Protocol Deviations - subject level - by category

Table 9-2 Summary of important protocol deviations at site and subject level

	Site	Subject	Total
Total	32	806	838
Assessment Deviations (incl. lab)		17	17
Incl./Excl./Rand. Criteria	5	171	176
Informed Consent	12	260	272
Other	15	358	373

Cross-reference: Appendix 16.2.2

Important protocol deviations closed or identified after database lock

There were no important protocol deviations identified after DBL.

10 Results

10.1 Participants

Participants were enrolled from 17 countries which included Croatia, Denmark, Finland, France, Germany, Greece, Ireland, Israel, Italy, Malaysia, Netherlands, Norway, Poland, Portugal, Romania, Spain and United Kingdom. Overall, 2601 patients with pre-existing diabetes mellitus were invited from all 17 countries, of which 155 patients refused to participate in the study. A total of 2446 patients (94.0%) were enrolled in the study. A country wise enrolment log of patient invitation and participation from each country is presented in Table 10-1 The maximum number of patients were enrolled in Denmark (627 patients) followed by Croatia (311 patients) and United Kingdom (306 patients). The least number of patients were enrolled in Greece (11 patients).

Of the 2446 enrolled patients a total of 73 patients were excluded from further analysis as they did not meet inclusion criteria or met exclusion criteria. The most common reason for exclusion from ALL analysis set was not meeting the inclusion criteria # 5 (of unchanged anti-diabetic treatment 4 weeks prior to and following conception) in 55 patients followed by meeting the exclusion criteria#1 (of women who had been pregnant for more than 16 weeks at baseline visit) in 12 patients. For details on patients excluded in ALL analysis set please see EOT Table 14.1.2.

Of the 2373 patients in FAS_MOTHER analysis set, 2209 patients (93.1%) completed the study and 164 patients (6.9%) discontinued the study (Table 10-2). The reasons for discontinuation were lost to follow-up (133 patients [14 patients before delivery and 119 patients after delivery]), withdrawal by the participant (18 patients), and “other reasons” (12 patients). One (1) patient discontinued the study due to adverse event. Please refer to EOT Table 14.1.57 for details on patients who discontinued the study in FAS MOTHER set, by delivery status. The number of patients who discontinued or completed the study in FAS_MOTHER analysis set, by country is presented in Table 10-2. The number of patients who discontinued or completed the study in MOTHER analysis set (excluding patients not on basal insulin and women changing basal insulin treatment after enrolment, please refer SAP, Appendix 16.1.7), by country is presented in EOT Table 14.1.4. Based on basal insulin treatment group at enrolment, all patients were divided in 3 groups: insulin detemir (n=764), other basal insulin (n=828) and no basal insulin (n=781). The records of patients who discontinued or completed the study in FAS_MOTHER analysis set and MOTHER analysis set, by basal insulin treatment group at enrolment are presented in EOT Table 14.1.5 and 14.1.6, respectively.

The number of patients who participated more than once in this study in FAS_MOTHER analysis set, and MOTHER analysis set, by country is presented in EOT Tables 14.1.7 and 14.1.8, respectively. The number of patients who participated more than once in this study in FAS_MOTHER analysis set and MOTHER analysis set, by treatment at enrolment is presented in EOT Table 14.1.9. and 14.1.10, respectively.

The number of patients who attended the planned visits in FAS_MOTHER analysis set and in MOTHER analysis set, by country is presented in EOT Tables 14.1.11 and 14.1.12, respectively. The number of patients who attended the planned visits in FAS MOTHER analysis set, MOTHER analysis set and ALL analysis set, by basal insulin treatment groups at enrolment is presented in EOT Tables 14.1.13, 14.1.14 and 14.1.15, respectively.

Table 10-1 Subject invitation and participation - country - Enrolment log

	Invited N	Enrolled N	Participation %
Total	2601	2446	94.0
Croatia	324	311	96.0
Denmark	643	627	97.5
Finland	155	150	96.8
France	178	165	92.7
Germany	35	35	100.0
Greece	11	11	100.0
Ireland	74	74	100.0
Israel	215	215	100.0
Italy	70	70	100.0
Malaysia	27	27	100.0
Netherlands	91	70	76.9
Norway	47	45	95.7
Poland	130	127	97.7
Portugal	21	19	90.5
Romania	26	26	100.0
Spain	185	168	90.8
United Kingdom	369	306	82.9

N: Number of patients, %: Percentage of patients

nis-primary/nn304-4016/current
18JUN2020:12:16:32 - t_invite/t_invite.txt

Cross-reference: EOT Table 14.1.1

Table 10-2 Subject disposition - discontinued and completed - country wise – FAS_MOTHER analysis set

	Discontinued on criteria*					Total Discontinued on criteria*	Completed on criteria**			Total Completed on criteria**
	1 N (%)	2 N (%)	3 N (%)	4 N (%)	5 N (%)	N (%)	1 N (%)	2 N (%)	3 N (%)	N (%)
Total(2373)	1(0.0)	18(0.8)	133(5.6)	12(0.5)		164(6.9)	1995(84.1)	213(9.0)	1(0.0)	2209(93.1)
Country										
Croatia(311)		3(1.0)	1(0.3)			4(1.3)	277(89.1)	30(9.6)		307(98.7)
Denmark(607)		1(0.2)	31(5.1)			32(5.3)	538(88.6)	37(6.1)		575(94.7)
Finland(148)			1(0.7)			1(0.7)	136(91.9)	11(7.4)		147(99.3)
France(161)		4(2.5)	17(10.6)	1(0.6)		22(13.7)	125(77.6)	13(8.1)	1(0.6)	139(86.3)
Germany(34)		1(2.9)	1(2.9)			2(5.9)	29(85.3)	3(8.8)		32(94.1)
Greece(11)							10(90.9)	1(9.1)		11(100)
Ireland(73)			9(12.3)			9(12.3)	53(72.6)	11(15.1)		64(87.7)
Israel(212)	1(0.5)	3(1.4)	7(3.3)			11(5.2)	175(82.5)	26(12.3)		201(94.8)
Italy(65)		2(3.1)				2(3.1)	60(92.3)	3(4.6)		63(96.9)
Malaysia(24)			1(4.2)			1(4.2)	21(87.5)	2(8.3)		23(95.8)
Netherlands(61)			1(1.6)			1(1.6)	54(88.5)	6(9.8)		60(98.4)
Norway(45)			1(2.2)	9(20.0)		10(22.2)	30(66.7)	5(11.1)		35(77.8)
Poland(127)		1(0.8)	1(0.8)			2(1.6)	111(87.4)	14(11.0)		125(98.4)
Portugal(18)			2(11.1)			2(11.1)	12(66.7)	4(22.2)		16(88.9)
Romania(26)							26(100)			26(100)
Spain(157)		1(0.6)	4(2.5)	1(0.6)		6(3.8)	139(88.5)	12(7.6)		151(96.2)
United Kingdom(293)		2(0.7)	56(19.1)	1(0.3)		59(20.1)	199(67.9)	35(11.9)		234(79.9)

N: Number of patients, %: Percentage of patients
*Criteria: 1: Adverse event, 2: withdrawal by the participant, 3: lost to follow-up, 4: other reason for discontinuation, 5: Missing.
**Criteria: 1: completion of the 1-year infant examination, 2: death of foetus/infant, 3: Missing.

nis-primary/nn304-4016/current
18JUN2020:12:16:23 - t_disp/t_disp_fas_mother.txt

Cross-reference: EOT Table 14.1.3

10.2 Descriptive data

Based on pooled data from 17 countries, the baseline demographics and characteristics of patients in FAS_MOTHER analysis set, and MOTHER analysis set, by basal insulin treatment group at enrolment are summarised in Table 10-3. and EOT Table 14.1.17, respectively. The descriptive data for each parameter did not include the non-responders to the variable in question (for details please see section 9.5.2). The baseline characteristics of patients by basal insulin treatment group at enrolment before and after propensity score matching in PRIMARY analysis set are summarised in EOT Table 14.1.33 and EOT Table 14.1.34, respectively. For all primary and secondary endpoints both crude and confounder adjusted analyses were performed, however for some endpoints (e.g. induced abortion by organ), there were not enough events to do an adjusted analysis. The crude analysis did not take into account confounding due to differences between the two treatment groups. Potential confounding was adjusted for by propensity score matching (binary endpoints) or multiple regression analysis (continuous endpoints).

10.2.1 Demographic and socioeconomic information

The mean age of patients across all groups from FAS_MOTHER analysis set was comparable. Mean age of pooled patient population was 30.85 years. Out of 2373 patients in the FAS_MOTHER analysis set, a majority of them (94.3%) were reported as being white. With regards to relevant socioeconomic parameters, 8.3% patients were current smoker and 1.1% patients were alcohol user at enrolment.

10.2.2 Obstetric history

The obstetric history of patients across all groups from the FAS_MOTHER analysis set is presented in Table 10-3. A total of 35.2% patients had no history of previous pregnancy, 32.6% patients had 1 previous pregnancy and 32.2% patients had 2 or more previous pregnancies. A total of 45.2% patients had no history of previous live births and it was their first pregnancy. A total of 53.6% patients reported pregnancy complications. Among the patients across all groups, history of pre-eclampsia (4.7% patients), caesarean section (20.9% patients), perinatal death (1.6% patients), preterm delivery (6.7% patients), spontaneous abortion (22.7% patients), malformations (2.1% [0.5% minor malformations and 1.6% major malformations]) and other pregnancy complications (13.2% patients) were reported at enrolment.

10.2.3 Medical history

The most commonly reported medical history (more than 5%) in patients across all groups in FAS_MOTHER analysis set was “thyroid disorder” (27.0% patients) followed by “psychiatric disorder” (8.3% patients) “hypertension” (7.8% patients), and “asthma” (5.3% patients). For more details refer to Table 10-3.

10.2.4 Diabetes history

Patients with a history of DM, across all groups from the FAS_MOTHER analysis set are presented in Table 10-3. At enrolment, a total of 89.1% patients had history of T1DM, and 10.9% patients had history of T2DM. The mean (SD) diabetes duration was 14.88 (8.48) years with the longest duration in patients on no basal insulin [13.13 (8.16) years in patients on insulin detemir, 13.54 (8.47) years in patients on other basal insulin, and 17.99 (7.92) years in patients on no basal insulins at enrolment]. The mean diabetes duration was comparable in patients on insulin detemir and patients on other basal insulin. A total of 13.1% patients had diabetes duration of <5 years and 86.9% patients had diabetes duration of ≥5 years. History of diabetes complications was reported in 29.0% patients. For details of other systemic complications in patients from FAS_MOTHER analysis set refer to Table 10-3.

10.2.5 Current pregnancy

At enrolment the mean gestational age of patients across all treatment groups in FAS_MOTHER analysis set was 8.65 weeks and was comparable across all groups (Table 10-3). A total of 21.7% patients had mean gestational age of <7 years, 64.4% patients had mean gestational age of ≥7-12 years and 13.9% patients had mean gestational age of ≥12-16 years. Of 2336 patients, folic acid was taken by 76.2% patients, before and during first trimester.

10.2.6 HbA_{1c}, anthropometric measurements and vital signs at enrolment

The HbA_{1c} (%) and other vital signs at enrolment, of patients across all groups from the FAS_MOTHER analysis set are presented in Table 10-3. The mean (SD) baseline HbA_{1c} (%) of patients across all groups in FAS_MOTHER analysis set was 7.01 (1.25) [7.00 (1.30), 7.19 (1.42), and 6.81 (0.94) in patients on insulin detemir, other basal insulin and no basal insulin, respectively].

The mean body weight was comparable across all groups. The mean (SD) baseline body weight of the pooled population was 72.87 (15.93) kg [71.10 (16.12) kg, 73.82 (16.77) kg, and 73.62 (14.62) kg in patients on insulin detemir, other basal insulin and no basal insulin, respectively].

The mean (SD) BMI of the pooled population was 26.38 (5.50) kg/m^2 [25.81 (5.75) kg/m^2, 26.82 (5.71) kg/m^2, and 26.46 (4.94) kg/m^2 in patients on insulin detemir, other basal insulin and no basal insulin, respectively]. BMI was <18.5 in 1.1% patients, ≥18.5 to 25.0 in 47.6% patients, ≥25.0 to 30.0 in 30.9% patients, ≥30.0 to 35.0 in 12.6% patients, ≥35.0 to 40.0 in 5.0% patients, and ≥40.0 in 2.9% patients.

10.2.7 Classes of anti-diabetic treatment at enrolment

Of the 2373 patients at the time of enrolment, 67.1% patients were on basal insulin, 97.6% patients were on bolus insulin, 0.8% patients were on premix insulin, 3.5% patients were on oral anti-

diabetic drugs, and 0.1% patients were on GLP-1 RA across all groups in FAS_MOTHER analysis set (details in Table 10-3).

Table 10-3 Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
Number of subjects	764		828		781		2373	
Demographic and socioeconomic information								
Country, N(%)								
N	764		828		781		2373	
Croatia	240	(31.4)	47	(5.7)	24	(3.1)	311	(13.1)
Denmark	127	(16.6)	282	(34.1)	198	(25.4)	607	(25.6)
Finland	59	(7.7)	53	(6.4)	36	(4.6)	148	(6.2)
France	15	(2.0)	39	(4.7)	107	(13.7)	161	(6.8)
Germany	4	(0.5)	11	(1.3)	19	(2.4)	34	(1.4)
Greece	4	(0.5)	7	(0.8)			11	(0.5)
Ireland	28	(3.7)	34	(4.1)	11	(1.4)	73	(3.1)
Israel	65	(8.5)	17	(2.1)	130	(16.6)	212	(8.9)
Italy	16	(2.1)	27	(3.3)	22	(2.8)	65	(2.7)
Malaysia	6	(0.8)	17	(2.1)	1	(0.1)	24	(1.0)
Netherlands	13	(1.7)	6	(0.7)	42	(5.4)	61	(2.6)
Norway	5	(0.7)	22	(2.7)	18	(2.3)	45	(1.9)
Poland	20	(2.6)	41	(5.0)	66	(8.5)	127	(5.4)
Portugal	4	(0.5)	13	(1.6)	1	(0.1)	18	(0.8)
Romania	22	(2.9)	1	(0.1)	3	(0.4)	26	(1.1)
Spain	27	(3.5)	92	(11.1)	38	(4.9)	157	(6.6)
United Kingdom	109	(14.3)	119	(14.4)	65	(8.3)	293	(12.3)
Age								
N	764		828		781		2373	
Mean (SD)	31.04	(5.12)	30.56	(5.30)	30.96	(4.90)	30.85	(5.12)
Median	31.00		30.00		31.00		31.00	
2.5; 97.5 percentiles	21.00; 40.00		21.00; 41.00		22.00; 41.00		21.00; 41.00	
Min, Max	18.00; 44.00		17.00; 47.00		18.00; 44.00		17.00; 47.00	

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
Race, N(%)								
N	749		789		669		2207	
Asian	13	(1.7)	33	(4.2)	2	(0.3)	48	(2.2)
Black or African American	8	(1.1)	10	(1.3)	1	(0.1)	19	(0.9)
Native Hawaiian or other Pacific Islander			1	(0.1)			1	(<0.1)
White	715	(95.5)	713	(90.4)	653	(97.6)	2081	(94.3)
Other	13	(1.7)	32	(4.1)	13	(1.9)	58	(2.6)
Education, N(%)								
N	701		741		675		2117	
University degree	210	(30.0)	169	(22.8)	285	(42.2)	664	(31.4)
College degree	90	(12.8)	122	(16.5)	131	(19.4)	343	(16.2)
Graduate school	133	(19.0)	97	(13.1)	80	(11.9)	310	(14.6)
Technical school	49	(7.0)	52	(7.0)	46	(6.8)	147	(6.9)
High school	103	(14.7)	115	(15.5)	57	(8.4)	275	(13.0)
A levels	25	(3.6)	22	(3.0)	12	(1.8)	59	(2.8)
Intermediate school leaving certificate	20	(2.9)	46	(6.2)	26	(3.9)	92	(4.3)
Basic school leaving certificate	22	(3.1)	36	(4.9)	10	(1.5)	68	(3.2)
Primary school	8	(1.1)	16	(2.2)	6	(0.9)	30	(1.4)
No education	4	(0.6)	14	(1.9)	2	(0.3)	20	(0.9)
Other	37	(5.3)	52	(7.0)	20	(3.0)	109	(5.1)
Occupation, N(%)								
N	724		782		734		2240	
Managerial (employed or self-employed)	100	(13.8)	43	(5.5)	55	(7.5)	198	(8.8)
Professional and higher technical	132	(18.2)	134	(17.1)	185	(25.2)	451	(20.1)
Clerical or lower technical	76	(10.5)	68	(8.7)	63	(8.6)	207	(9.2)
Skilled worker	182	(25.1)	180	(23.0)	227	(30.9)	589	(26.3)
Semiskilled worker	40	(5.5)	58	(7.4)	28	(3.8)	126	(5.6)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
Unskilled worker	16	(2.2)	49	(6.3)	28	(3.8)	93	(4.2)
Student	27	(3.7)	47	(6.0)	41	(5.6)	115	(5.1)
Not working	116	(16.0)	153	(19.6)	74	(10.1)	343	(15.3)
Other	35	(4.8)	50	(6.4)	33	(4.5)	118	(5.3)
Tobacco , N(%)								
N	746		799		766		2311	
Never	583	(78.2)	579	(72.5)	592	(77.3)	1754	(75.9)
Previous	92	(12.3)	142	(17.8)	132	(17.2)	366	(15.8)
Current	71	(9.5)	78	(9.8)	42	(5.5)	191	(8.3)
Alcohol , N(%)								
N	734		782		748		2264	
Yes	7	(1.0)	12	(1.5)	6	(0.8)	25	(1.1)
No	727	(99.0)	770	(98.5)	742	(99.2)	2239	(98.9)
Obstetric history								
Number of previous pregnancies, N(%)								
N	763		828		781		2372	
0	243	(31.8)	289	(34.9)	302	(38.7)	834	(35.2)
1	275	(36.0)	276	(33.3)	223	(28.6)	774	(32.6)
2	121	(15.9)	135	(16.3)	146	(18.7)	402	(16.9)
3	64	(8.4)	68	(8.2)	56	(7.2)	188	(7.9)
4+	60	(7.9)	60	(7.2)	54	(6.9)	174	(7.3)
Number of previous live births, N(%)								
N	742		756		734		2232	
0	344	(46.4)	329	(43.5)	335	(45.6)	1008	(45.2)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
1	292	(39.4)	311	(41.1)	283	(38.6)	886	(39.7)
2	80	(10.8)	91	(12.0)	87	(11.9)	258	(11.6)
3	14	(1.9)	20	(2.6)	18	(2.5)	52	(2.3)
4+	12	(1.6)	5	(0.7)	11	(1.5)	28	(1.3)
Previous Pregnancy Complications (Y/N), N(%)								
N	729		738		687		2154	
Yes	390	(53.5)	404	(54.7)	360	(52.4)	1154	(53.6)
No	339	(46.5)	334	(45.3)	327	(47.6)	1000	(46.4)
Previous pre-eclampsia, N(%)								
N	764		828		781		2373	
Yes	29	(3.8)	37	(4.5)	45	(5.8)	111	(4.7)
No	735	(96.2)	791	(95.5)	736	(94.2)	2262	(95.3)
Previous caesarean section, N(%)								
N	764		828		781		2373	
Yes	179	(23.4)	146	(17.6)	171	(21.9)	496	(20.9)
No	585	(76.6)	682	(82.4)	610	(78.1)	1877	(79.1)
Previous perinatal deaths, N(%)								
N	764		828		781		2373	
Yes	14	(1.8)	13	(1.6)	10	(1.3)	37	(1.6)
No	750	(98.2)	815	(98.4)	771	(98.7)	2336	(98.4)
Previous preterm delivery , N(%)								
N	764		828		781		2373	
Yes	47	(6.2)	63	(7.6)	50	(6.4)	160	(6.7)
No	717	(93.8)	765	(92.4)	731	(93.6)	2213	(93.3)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
Previous spontaneous abortion, N(%)								
N	764		828		781		2373	
Yes	194	(25.4)	180	(21.7)	165	(21.1)	539	(22.7)
No	570	(74.6)	648	(78.3)	616	(78.9)	1834	(77.3)
Previous malformations, N(%)								
N	764		828		781		2373	
Yes	17	(2.2)	18	(2.2)	15	(1.9)	50	(2.1)
No	747	(97.8)	810	(97.8)	766	(98.1)	2323	(97.9)
Previous minor malformations, N(%)								
N	764		828		781		2373	
Yes	2	(0.3)	7	(0.8)	3	(0.4)	12	(0.5)
No	762	(99.7)	821	(99.2)	778	(99.6)	2361	(99.5)
Previous major malformations, N(%)								
N	764		828		781		2373	
Yes	15	(2.0)	11	(1.3)	12	(1.5)	38	(1.6)
No	749	(98.0)	817	(98.7)	769	(98.5)	2335	(98.4)
Other pregnancy complications								
N	764		828		781		2373	
Yes	88	(11.5)	128	(15.5)	98	(12.5)	314	(13.2)
No	676	(88.5)	700	(84.5)	683	(87.5)	2059	(86.8)
Medical history								
Hypertension, N(%)								
N	764		827		781		2372	

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
Yes	64	(8.4)	69	(8.3)	53	(6.8)	186	(7.8)
No	700	(91.6)	758	(91.7)	728	(93.2)	2186	(92.2)
Epilepsy, N(%)								
N	761		827		781		2369	
Yes	13	(1.7)	15	(1.8)	10	(1.3)	38	(1.6)
No	748	(98.3)	812	(98.2)	771	(98.7)	2331	(98.4)
Thyroid disorder, N(%)								
N	763		825		780		2368	
Yes	183	(24.0)	198	(24.0)	258	(33.1)	639	(27.0)
No	580	(76.0)	627	(76.0)	522	(66.9)	1729	(73.0)
Asthma, N(%)								
N	762		827		779		2368	
Yes	34	(4.5)	51	(6.2)	40	(5.1)	125	(5.3)
No	728	(95.5)	776	(93.8)	739	(94.9)	2243	(94.7)
Heart disease, N(%)								
N	763		825		780		2368	
Yes	5	(0.7)	11	(1.3)	7	(0.9)	23	(1.0)
No	758	(99.3)	814	(98.7)	773	(99.1)	2345	(99.0)
Psychiatric disorder, N(%)								
N	764		825		780		2369	
Yes	54	(7.1)	71	(8.6)	71	(9.1)	196	(8.3)
No	710	(92.9)	754	(91.4)	709	(90.9)	2173	(91.7)
Inheritable diseases, N(%)								

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER

	Insulin detemir	Other basal insulin	No basal insulin	Total
N	759	822	778	2359
Yes	28 (3.7)	31 (3.8)	16 (2.1)	75 (3.2)
No	731 (96.3)	791 (96.2)	762 (97.9)	2284 (96.8)
Diabetes history				
Type of DM, N(%)				
N	764	828	781	2373
T1DM	625 (81.8)	730 (88.2)	760 (97.3)	2115 (89.1)
T2DM	139 (18.2)	98 (11.8)	21 (2.7)	258 (10.9)
Diabetes duration				
N	760	821	781	2362
Mean (SD)	13.13 (8.16)	13.54 (8.47)	17.99 (7.92)	14.88 (8.48)
Median	12.00	13.00	18.00	15.00
2.5; 97.5 percentiles	2.00; 30.00	2.00; 30.00	4.00; 33.00	2.00; 31.00
Min, Max	1.00; 37.00	1.00; 38.00	1.00; 40.00	1.00; 40.00
Diabetes duration, N(%)				
N	760	821	781	2362
<5 years	129 (17.0)	148 (18.0)	32 (4.1)	309 (13.1)
>= 5 years	631 (83.0)	673 (82.0)	749 (95.9)	2053 (86.9)
History of diabetes complications, N(%)				
N	762	826	781	2369
Yes	194 (25.5)	198 (24.0)	294 (37.6)	686 (29.0)
No	568 (74.5)	628 (76.0)	487 (62.4)	1683 (71.0)
History of microvascular complications, N(%)				

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
N	762		824		781		2367	
Yes	194	(25.5)	198	(24.0)	293	(37.5)	685	(28.9)
No	568	(74.5)	626	(76.0)	488	(62.5)	1682	(71.1)
History of macrovascular complications, N(%)								
N	761		825		781		2367	
Yes	2	(0.3)	3	(0.4)	3	(0.4)	8	(0.3)
No	759	(99.7)	822	(99.6)	778	(99.6)	2359	(99.7)
History of retinopathy, N(%)								
N	761		821		779		2361	
Yes	162	(21.3)	184	(22.4)	271	(34.8)	617	(26.1)
No	599	(78.7)	637	(77.6)	508	(65.2)	1744	(73.9)
History of neuropathy, N(%)								
N	761		821		780		2362	
Yes	32	(4.2)	10	(1.2)	27	(3.5)	69	(2.9)
No	729	(95.8)	811	(98.8)	753	(96.5)	2293	(97.1)
History of nephropathy, N(%)								
N	760		823		780		2363	
Yes	36	(4.7)	33	(4.0)	35	(4.5)	104	(4.4)
No	724	(95.3)	790	(96.0)	745	(95.5)	2259	(95.6)
History of macroangiopathy (including peripheral vascular disease), N(%)								
N	761		823		779		2363	
Yes	2	(0.3)	2	(0.2)	3	(0.4)	7	(0.3)
No	759	(99.7)	821	(99.8)	776	(99.6)	2356	(99.7)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER

	Insulin detemir	Other basal insulin	No basal insulin	Total
History of unstable angina, N(%)				
N	756	823	775	2354
Yes		1 (0.1)		1 (<0.1)
No	756 (100.0)	822 (99.9)	775 (100.0)	2353 (100)
History of heart failure, N(%)				
N	743	822	774	2339
No	743 (100.0)	822 (100.0)	774 (100.0)	2339 (100.0)
Current pregnancy				
Gestational age at enrolment (weeks)				
N	760	821	781	2362
Mean (SD)	8.72 (2.48)	8.82 (2.59)	8.41 (2.50)	8.65 (2.53)
Median	8.00	8.00	8.00	8.00
2.5; 97.5 percentiles	5.00; 14.00	4.00; 15.00	4.00; 14.00	4.00; 14.00
Min, Max	2.00; 16.00	2.00; 16.00	2.00; 16.00	2.00; 16.00
Gestational age at enrolment (weeks), N(%)				
N	760	821	781	2362
<7	156 (20.5)	164 (20.0)	184 (23.6)	504 (21.3)
>=7 - 12	494 (65.0)	528 (64.3)	506 (64.8)	1528 (64.7)
>=12 - 16	110 (14.5)	129 (15.7)	91 (11.7)	330 (14.0)
Folic acid taken before and during first trimester, N(%)				
N	754	820	762	2336
Yes	484 (64.2)	644 (78.5)	651 (85.4)	1779 (76.2)
No	270 (35.8)	176 (21.5)	111 (14.6)	557 (23.8)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER

	Insulin detemir	Other basal insulin	No basal insulin	Total
HbA1c, anthropometric measurements and vital signs at enrolment				
HbA1c				
N	724	777	737	2238
Mean (SD)	7.00 (1.30)	7.19 (1.42)	6.81 (0.94)	7.01 (1.25)
Median	6.73	6.82	6.70	6.73
2.5; 97.5 percentiles	5.20; 10.50	5.35; 10.60	5.35; 9.10	5.30; 10.20
Min, Max	4.40; 13.90	4.71; 14.50	4.70; 13.90	4.40; 14.50
HbA1c (<7%), N(%)				
N	724	777	737	2238
Yes	433 (59.8)	435 (56.0)	495 (67.2)	1363 (60.9)
No	291 (40.2)	342 (44.0)	242 (32.8)	875 (39.1)
HbA1c (<6.5%), N(%)				
N	724	777	737	2238
Yes	282 (39.0)	279 (35.9)	273 (37.0)	834 (37.3)
No	442 (61.0)	498 (64.1)	464 (63.0)	1404 (62.7)
HbA1c%), N(%)				
N	724	777	737	2238
<5.5	45 (6.2)	34 (4.4)	27 (3.7)	106 (4.7)
>= 5.5 to 6.0	102 (14.1)	100 (12.9)	81 (11.0)	283 (12.6)
>=6.0 to 6.5	135 (18.6)	145 (18.7)	165 (22.4)	445 (19.9)
>=6.5 to 7.0	151 (20.9)	156 (20.1)	222 (30.1)	529 (23.6)
>=7.0 to 7.5	88 (12.2)	77 (9.9)	105 (14.2)	270 (12.1)
>=7.5 to 8.0	70 (9.7)	71 (9.1)	66 (9.0)	207 (9.2)
>=8.0 to 8.5	46 (6.4)	70 (9.0)	31 (4.2)	147 (6.6)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER

	Insulin detemir	Other basal insulin	No basal insulin	Total
>=8.5 to 9.0	29 (4.0)	39 (5.0)	18 (2.4)	86 (3.8)
>=9.0 to 9.5	19 (2.6)	36 (4.6)	10 (1.4)	65 (2.9)
>=9.5	39 (5.4)	49 (6.3)	12 (1.6)	100 (4.5)
Weight (kg)				
N	736	794	729	2259
Mean (SD)	71.10 (16.12)	73.82 (16.77)	73.62 (14.62)	72.87 (15.93)
Median	67.30	70.00	71.10	70.00
2.5; 97.5 percentiles	50.30; 115.00	51.00; 117.00	53.20; 107.30	51.00; 115.00
Min, Max	43.00; 150.00	44.00; 141.60	45.20; 183.00	43.00; 183.00
BMI (kg/m2)				
N	734	788	724	2246
Mean (SD)	25.81 (5.75)	26.82 (5.71)	26.46 (4.94)	26.38 (5.50)
Median	24.30	25.45	25.60	25.10
2.5; 97.5 percentiles	18.60; 40.80	19.10; 41.90	19.90; 37.80	19.00; 40.60
Min, Max	16.30; 52.50	16.40; 49.00	17.50; 66.40	16.30; 66.40
BMI (kg/m2)%), N(%)				
N	734	788	724	2246
<18.5	14 (1.9)	8 (1.0)	2 (0.3)	24 (1.1)
>= 18.5 to 25.0	401 (54.6)	360 (45.7)	307 (42.4)	1068 (47.6)
>=25.0 to 30.0	182 (24.8)	234 (29.7)	279 (38.5)	695 (30.9)
>=30.0 to 35.0	76 (10.4)	108 (13.7)	98 (13.5)	282 (12.6)
>=35.0 to 40.0	39 (5.3)	48 (6.1)	25 (3.5)	112 (5.0)
>=40.0	22 (3.0)	30 (3.8)	13 (1.8)	65 (2.9)
Systolic blood pressure (mmHg)				
N	704	748	667	2119

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER

	Insulin detemir	Other basal insulin	No basal insulin	Total
Mean (SD)	117.53 (13.67)	119.23 (13.76)	118.57 (13.19)	118.46 (13.57)
Median	119.00	120.00	119.00	119.00
2.5; 97.5 percentiles	90.00; 146.00	95.00; 149.00	95.00; 145.00	92.00; 146.00
Min, Max	80.00; 183.00	83.00; 188.00	80.00; 198.00	80.00; 198.00
Systolic blood pressure (mmHg)%), N(%)				
N	704	748	667	2119
<130	563 (80.0)	576 (77.0)	535 (80.2)	1674 (79.0)
>=130 to 140	101 (14.3)	116 (15.5)	98 (14.7)	315 (14.9)
>=140	40 (5.7)	56 (7.5)	34 (5.1)	130 (6.1)
Diastolic blood pressure (mmHg)				
N	704	748	667	2119
Mean (SD)	71.85 (9.90)	73.48 (9.16)	72.03 (9.55)	72.48 (9.56)
Median	70.00	73.00	72.00	72.00
2.5; 97.5 percentiles	55.00; 91.00	59.00; 93.00	51.00; 90.00	55.00; 92.00
Min, Max	45.00; 111.00	45.00; 112.00	39.00; 110.00	39.00; 112.00
Diastolic blood pressure(mmHg), N(%)				
N	704	748	667	2119
<85	639 (90.8)	658 (88.0)	607 (91.0)	1904 (89.9)
>=85 to 90	36 (5.1)	52 (7.0)	41 (6.1)	129 (6.1)
>=90	29 (4.1)	38 (5.1)	19 (2.8)	86 (4.1)
Current anti-diabetic treatment at enrolment				
Basal insulin at enrolment, N(%)				
N	764	828	781	2373
Yes	764 (100.0)	828 (100.0)		1592 (67.1)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment groups and no basal insulin group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
No					781	(100.0)	781	(32.9)
Bolus insulin at enrolment, N(%)								
N	764		828		781		2373	
Yes	749	(98.0)	803	(97.0)	765	(98.0)	2317	(97.6)
No	15	(2.0)	25	(3.0)	16	(2.0)	56	(2.4)
Premix insulin at enrolment, N(%)								
N	764		828		781		2373	
Yes	1	(0.1)	2	(0.2)	15	(1.9)	18	(0.8)
No	763	(99.9)	826	(99.8)	766	(98.1)	2355	(99.2)
OAD at enrolment, N(%)								
N	764		828		781		2373	
Yes	39	(5.1)	35	(4.2)	10	(1.3)	84	(3.5)
No	725	(94.9)	793	(95.8)	771	(98.7)	2289	(96.5)
GLP-1 RA at enrolment, N(%)								
N	764		828		781		2373	
Yes					3	(0.4)	3	(0.1)
No	764	(100.0)	828	(100.0)	778	(99.6)	2370	(99.9)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Cross-reference: Modified from EOT Table 14.1.16

10.2.8 Foetus, infant and delivery characteristics

Summaries of foetus characteristics in FAS_FOETUS analysis set, FOETUS analysis set, FAS_LIVEBORN analysis set and LIVEBORN analysis set, by mother's basal insulin treatment group at enrolment are presented in EOT Table 14.1.18, EOT Table 14.1.19, EOT Table 14.1.20 and EOT Table 14.1.21, respectively. Summaries of infant's characteristics in FAS_INFANT analysis set, and INFANT analysis set, by mother's basal insulin treatment group at enrolment are presented in EOT Table 14.1.22, and EOT Table 14.1.23, respectively.

10.2.9 Dosage of study product

A summary of observed insulin dose during pregnancy in FAS_MOTHER analysis set, by basal insulin treatment group at enrolment is presented in EOT Table 14.1.26. At baseline 757 patients on insulin detemir were on a mean basal insulin dose of 28.09 units and 824 patients on other basal insulin were on a mean basal insulin dose of 25.68 units. At baseline 720 patients on insulin detemir were on a mean bolus insulin dose of 26.27 units, 774 patients on other basal insulin were on a mean bolus insulin dose of 26.51 units and 702 patients on no basal insulin were on a mean bolus insulin dose of 41.68 units. At baseline 759 patients on insulin detemir were on a mean total insulin dose of 52.98 units, 826 patients on other basal insulin were on a mean total insulin dose of 50.62 units and 713 patients on no basal insulin were on a mean total insulin dose of 42.21 units. A summary of observed insulin dose during pregnancy in MOTHER analysis set, by basal insulin treatment group at enrolment is presented in EOT Table 14.1.27.

10.2.10 Concomitant medications

A summary of glucose-lowering treatment and selected concomitant medication used by mothers in FAS_MOTHER analysis set, during pregnancy is presented in Table 10-4 (for detailed list please refer to EOT Table 14.1.28). A summary of glucose-lowering treatment and concomitant medication used by mothers in MOTHER analysis set, during pregnancy is presented in EOT Table 14.1.29. Summaries of medication that the foetus/infant in FAS_FOETUS analysis set, and FOETUS analysis set were exposed to, at any time during the study are presented in EOT Table 14.1.30 and EOT Table 14.1.31, respectively.

Table 10-4 Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Number of subjects	764	828	781	2373
Medication during Pregnancy				
At any time during pregnancy, N (%)				
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	3 (0.4)	6 (0.7)	3 (0.4)	12 (0.5)
ACE INHIBITORS AND DIURETICS		1 (0.1)		1 (0.0)
ACE INHIBITORS, PLAIN	3 (0.4)	5 (0.6)	2 (0.3)	10 (0.4)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
ANALGESICS	76 (9.9)	119 (14.4)	115 (14.7)	310 (13.1)
ANILIDES	62 (8.1)	104 (12.6)	93 (11.9)	259 (10.9)
MORPHINAN DERIVATIVES			1 (0.1)	1 (0.0)
NATURAL OPIUM ALKALOIDS	17 (2.2)	28 (3.4)	36 (4.6)	81 (3.4)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	11 (1.4)	13 (1.6)	16 (2.0)	40 (1.7)
OTHER ANALGESICS AND ANTIPYRETICS	3 (0.4)	8 (1.0)	14 (1.8)	25 (1.1)
OTHER OPIOIDS	4 (0.5)	4 (0.5)	6 (0.8)	14 (0.6)
PHENYLPIPERIDINE DERIVATIVES	3 (0.4)	6 (0.7)	1 (0.1)	10 (0.4)
PYRAZOLONES	5 (0.7)	6 (0.7)	4 (0.5)	15 (0.6)
SELECTIVE SEROTONIN (5HT1) AGONISTS		2 (0.2)	5 (0.6)	7 (0.3)
Not coded	3 (0.4)	3 (0.4)	1 (0.1)	7 (0.3)
ANTIEPILEPTICS	7 (0.9)	4 (0.5)	2 (0.3)	13 (0.5)
FATTY ACID DERIVATIVES	4 (0.5)	2 (0.2)		6 (0.3)
OTHER ANTIEPILEPTICS	3 (0.4)	3 (0.4)	2 (0.3)	8 (0.3)
BETA BLOCKING AGENTS	44 (5.8)	82 (9.9)	51 (6.5)	177 (7.5)
ALPHA AND BETA BLOCKING AGENTS	38 (5.0)	75 (9.1)	50 (6.4)	163 (6.9)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
BETA BLOCKING AGENTS, NON-SELECTIVE	1 (0.1)		1 (0.1)	2 (0.1)
BETA BLOCKING AGENTS, SELECTIVE	5 (0.7)	7 (0.8)	1 (0.1)	13 (0.5)
CALCIUM CHANNEL BLOCKERS	4 (0.5)	5 (0.6)	14 (1.8)	23 (1.0)
DIHYDROPYRIDINE DERIVATIVES	4 (0.5)	5 (0.6)	14 (1.8)	23 (1.0)
LIPID MODIFYING AGENTS	1 (0.1)	5 (0.6)	8 (1.0)	14 (0.6)
HMG COA REDUCTASE INHIBITORS	1 (0.1)	4 (0.5)	7 (0.9)	12 (0.5)
OTHER LIPID MODIFYING AGENTS		1 (0.1)	1 (0.1)	2 (0.1)
During first trimester, N (%)				
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	3 (0.4)	4 (0.5)	3 (0.4)	10 (0.4)
ACE INHIBITORS AND DIURETICS		1 (0.1)		1 (0.0)
ACE INHIBITORS, PLAIN	3 (0.4)	3 (0.4)	2 (0.3)	8 (0.3)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
ANALGESICS	9 (1.2)	19 (2.3)	7 (0.9)	35 (1.5)
ANILIDES	6 (0.8)	18 (2.2)	4 (0.5)	28 (1.2)
NATURAL OPIUM ALKALOIDS		2 (0.2)		2 (0.1)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS		1 (0.1)	2 (0.3)	3 (0.1)
OTHER OPIOIDS	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
PHENYLPIPERIDINE DERIVATIVES	1 (0.1)			1 (0.0)
PYRAZOLONES	1 (0.1)	1 (0.1)		2 (0.1)
SELECTIVE SEROTONIN (5HT1) AGONISTS			2 (0.3)	2 (0.1)
ANTIEPILEPTICS	7 (0.9)	4 (0.5)	2 (0.3)	13 (0.5)
FATTY ACID DERIVATIVES	4 (0.5)	2 (0.2)		6 (0.3)
OTHER ANTIEPILEPTICS	3 (0.4)	3 (0.4)	2 (0.3)	8 (0.3)
BETA BLOCKING AGENTS	14 (1.8)	19 (2.3)	13 (1.7)	46 (1.9)
ALPHA AND BETA BLOCKING AGENTS	9 (1.2)	15 (1.8)	13 (1.7)	37 (1.6)
BETA BLOCKING AGENTS, SELECTIVE	5 (0.7)	4 (0.5)		9 (0.4)
CALCIUM CHANNEL BLOCKERS	2 (0.3)	1 (0.1)	4 (0.5)	7 (0.3)
DIHYDROPYRIDINE DERIVATIVES	2 (0.3)	1 (0.1)	4 (0.5)	7 (0.3)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
During second trimester, N (%)				
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	3 (0.4)	2 (0.2)		5 (0.2)
ACE INHIBITORS AND DIURETICS		1 (0.1)		1 (0.0)
ACE INHIBITORS, PLAIN	3 (0.4)	1 (0.1)		4 (0.2)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	1 (0.1)			1 (0.0)
ANALGESICS	24 (3.1)	42 (5.1)	29 (3.7)	95 (4.0)
ANILIDES	21 (2.7)	34 (4.1)	20 (2.6)	75 (3.2)
NATURAL OPIUM ALKALOIDS	3 (0.4)	4 (0.5)	2 (0.3)	9 (0.4)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	2 (0.3)	6 (0.7)	5 (0.6)	13 (0.5)
OTHER ANALGESICS AND ANTIPYRETICS			1 (0.1)	1 (0.0)
OTHER OPIOIDS	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
PHENYLPIPERIDINE DERIVATIVES	1 (0.1)	3 (0.4)		4 (0.2)
PYRAZOLONES		2 (0.2)	1 (0.1)	3 (0.1)
SELECTIVE SEROTONIN (5HT1) AGONISTS		2 (0.2)	5 (0.6)	7 (0.3)
Not coded	1 (0.1)	2 (0.2)		3 (0.1)
ANTIEPILEPTICS	7 (0.9)	4 (0.5)	2 (0.3)	13 (0.5)
FATTY ACID DERIVATIVES	4 (0.5)	2 (0.2)		6 (0.3)
OTHER ANTIEPILEPTICS	3 (0.4)	3 (0.4)	2 (0.3)	8 (0.3)
ANTIHYPERTENSIVES	25 (3.3)	38 (4.6)	32 (4.1)	95 (4.0)
ALPHA-ADRENORECEPTOR ANTAGONISTS			1 (0.1)	1 (0.0)
HYDRAZINOPHTHALAZINE DERIVATIVES			1 (0.1)	1 (0.0)
METHYLDOPA	25 (3.3)	38 (4.6)	31 (4.0)	94 (4.0)
CALCIUM CHANNEL BLOCKERS	3 (0.4)	1 (0.1)	6 (0.8)	10 (0.4)
DIHYDROPYRIDINE DERIVATIVES	3 (0.4)	1 (0.1)	6 (0.8)	10 (0.4)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Cross-reference: Modified from EOT Table 14.1.28

10.3 Outcome data

FAS_MOTHER analysis set included 2373 patients. This set was used for analysis of SAEs and ADRs among mothers.

MOTHER analysis set included 1457 patients. This set was used for analyses of secondary effectiveness endpoint and secondary safety maternal endpoints.

PRIMARY analysis set included 1360 patients. This set was used for analyses of primary endpoint.

FAS_FOETUS analysis set included 2396 patients. This set was used for analysis of SAEs and ADRs among foetus/infants.

FOETUS analysis set included 1481 foetuses and this set was used for analyses of secondary pregnancy outcome safety endpoints and secondary infant safety endpoints.

LIVEBORN analysis set included 1351 infants included in the FOETUS analysis set, who were alive at delivery. The analysis set was used for analyses of secondary infant endpoints.

INFANT analysis set included 1268 infants and this set was used for analyses of secondary infant endpoints.

For more details of the analysis sets used for endpoints, please refer Appendix 16.1.7, Section 4.1.

10.4 Main results

10.4.1 Primary endpoint: proportion of pregnancies that did not result in major congenital malformations or perinatal death or neonatal death

The primary objective/endpoint of this study was to compare the proportion of pregnancies in patients treated with insulin detemir to the proportion of pregnancies in patients treated with other basal insulin regimens not resulting in major congenital malformations or perinatal death or neonatal death. The assessment was made only for events occurring from gestational week 22 to 4 weeks after delivery.

A summary of pregnancy outcomes that did not result in major malformations, perinatal death or neonatal death among foetus of women treated with insulin detemir treatment group compared to other basal insulins treatment group is presented in Table 10-4.

Primary analysis of primary endpoint

The primary endpoint was analysed in 1330 patients from PRIMARY analysis set (30 patients were not included due to missing outcome data). Of the 667 patients analysed in insulin detemir

treatment group, 647 pregnancies did not result in any adverse pregnancy outcome (major congenital malformations or perinatal death or neonatal death). A total of 20 events [6 events of perinatal death (2 pregnancies resulting in perinatal death, also resulted in major congenital malformations), 1 event of neonatal death and 15 events of major congenital malformations] were reported in patients on insulin detemir. Of the 663 patients analysed in other basal insulin treatment group, 633 pregnancies did not result in any adverse pregnancy outcome (major congenital malformations or perinatal death or neonatal death). A total of 30 events (13 events of perinatal death, and 17 events of major congenital malformations) were reported in patients on other basal insulin. There was no significant difference in the pregnancies not resulting in major congenital malformations or perinatal death or neonatal death observed with insulin detemir compared to other basal insulins. The absolute relative difference (RD) between the two treatment groups was 0.015 ([-0.01, 0.04]$_{95\%CI}$, p=0.1518). The odds ratio (OR) (relative difference) between the two treatment groups was 1.533 (0.86, 2.73). Please refer to section 10.4.2.2 for details on number of perinatal death, neonatal death, and major congenital malformations before propensity score matching among foetus of women treated with insulin detemir treatment group compared to other basal insulins treatment group.

Additional analysis of primary endpoint

An additional analysis for primary endpoints after propensity score matching (see details in Appendix 16.1.7, Section 7.1) was done in 770 patients (385 patients each in insulin detemir and other basal insulin treatment group). There was no difference in the pregnancies not resulting in major congenital malformations or perinatal death or neonatal death observed with insulin detemir treatment group compared to other basal insulins treatment group. The absolute RD between the two treatment groups was -0.003 ([-0.03, 0.03]$_{95\%CI}$, p=0.8575). The OR between the two treatment groups was 0.939 (0.47, 1.89).Table 10-4. Please refer to section 10.4.2.2 for details on number of perinatal death, neonatal death, and major congenital malformations after propensity score matching among foetus of women treated with insulin detemir treatment group compared to other basal insulins treatment group.

Table 10-4 Pregnancy outcomes not resulting in major malformations, perinatal death or neonatal death among foetus of women treated with basal insulin detemir compared to other basal insulins - summary – Primary analysis set

	N	Events*	Risk/Odds		95% CI	P-value
N = 1330						
Before propensity score matching						
Insulin detemir	667	647	0.97/32.35			
Other basal insulin	663	633	0.95/21.10			
Insulin detemir vs Other basal insulin						
Risk difference				0.015	[-0.01, 0.04]	0.1518
Odds ratio				1.533	[0.86, 2.73]	
N = 770						
After propensity score matching						
Insulin detemir	385	368	0.96/21.65			
Other basal insulin	385	369	0.96/23.06			
Insulin detemir vs Other basal insulin						
Risk difference				-0.003	[-0.03, 0.03]	0.8575
Odds ratio				0.939	[0.47, 1.89]	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

*Events in this table are the pregnancy outcomes not resulting in major malformations, perinatal death or neonatal death.

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Cross-reference: Modified from EOT Table 14.1.32

10.4.2 Secondary endpoints

10.4.2.1 Maternal effectiveness endpoints

HbA_{1c} during pregnancy

Available HbA_{1c} measurements were collected at baseline visit, at standard visits during pregnancy, and at delivery. Each measurement were then assigned to either conception, end of first trimester, end of second trimester, or end of third trimester.

Summaries of observed HbA_{1c} during pregnancy in patients in FAS_MOTHER analysis set and MOTHER analysis set are presented in EOT Table 14.1.24 and EOT Table 14.1.25, respectively. A summary of estimated HbA_{1c} (%) and the statistical analysis of estimated mean HbA_{1c} (%) during pregnancy in women treated with basal insulin detemir treatment group compared to other basal insulin treatment group in MOTHER analysis set are presented in EOT Table 14.1.35 and EOT Table 14.1.36, respectively.

The crude model treatment difference in estimated mean HbA_{1c} (%) (insulin detemir versus other basal insulin) in 1454 patients was as follows:

At conception: -0.145 (-0.350, 0.059)$_{95\%CI}$, p=0.1633
At the end of first trimester: -0.181 (-0.300, -0.062)$_{95\%CI}$, p= 0.0029
At the end of second trimester: -0.139 (-0.232, -0.046)$_{95\%CI}$, p=0.0034
At the end of third trimester: -0.085 (-0.184, 0.014)$_{95\%CI}$, p=0.0932

There was no significant interaction observed between time and basal insulin treatment group using crude model (p=0.18) suggesting that there was no significant difference in HbA_{1c} over time between the treatment groups.

The adjusted model treatment difference in estimated mean HbA_{1c} (%) (insulin detemir versus other basal insulin) in 1454 patients was as follows:

At conception: -0.051 (-0.280, 0.178)$_{95\%CI}$, p=0.6650
At the end of first trimester: -0.070 (-0.201, 0.061)$_{95\%CI}$, p= 0.2955
At the end of second trimester: -0.013 (-0.121, 0.094)$_{95\%CI}$, p=0.8049
At the end of third trimester: -0.015 (-0.101, 0.132)$_{95\%CI}$, p=0.7960

There was no significant interaction observed between time and basal insulin treatment group using adjusted model (p=0.51) suggesting that there was no significant difference in HbA_{1c} over time between the treatment groups.

Mean plot for observed HbA_{1c} during pregnancy by basal insulin treatment group at enrolment in MOTHER analysis set is presented in EOT Figure 14.2.1. Crude and adjusted plots for estimated HbA_{1c} during pregnancy by basal insulin treatment group at enrolment in MOTHER analysis set are

presented in EOT Figures 14.2.2 and 14.2.3, respectively. There was a tendency towards lower HbA_{1c} in the insulin detemir group in the crude model, however it disappeared after adjusting for differences in baseline characteristics between the two groups.

10.4.2.2 Maternal safety endpoints

Secondary Maternal safety Endpoints

Major hypoglycaemia during pregnancy

Summary of major hypoglycaemia during pregnancy in patients in FAS_MOTHER analysis set, and MOTHER analysis set are presented in EOT Table 14.1.24 and EOT Table 14.1.25, respectively.

A statistical analysis of major hypoglycaemia during pregnancy in patients, treated with basal insulin detemir compared to other basal insulins was performed before propensity score matching (crude model) in 1394 patients (697 patients on insulin detemir with 42 events, 697 patients on other basal insulins with 63 events) from MOTHER analysis set (Table 10-5). A significant difference was observed in the risk of major hypoglycaemia in patients on insulin detemir compared to other basal insulin (p=0.0419), favouring insulin detemir. The absolute RD between the two treatment groups was -0.030 (-0.058, -0.002)$_{95\%CI}$. The OR between the two treatment groups was 0.645 (0.430;0.968)$_{95\%CI}$.

Similar analysis was performed after propensity score matching (adjusted model) in 790 patients (395 patients on insulin detemir treatment with 35 events, 395 patients on other basal insulins treatment with 28 events). No significant difference was observed in the risk of major hypoglycaemia in patients on insulin detemir treatment group compared to other basal insulin (p=0.3701). The absolute RD between the two treatment groups was 0.018 (-0.021, 0.056)$_{95\%CI}$. The OR between the two treatment groups was 1.274 (0.759, 2.139)$_{95\%CI}$.

Forest plots illustrating RD (crude and adjusted models) and OR (crude and adjusted models) of major hypoglycaemia during pregnancy, in patients treated with basal insulin detemir compared to other basal insulins are presented in EOT Figures 14.2.4 and 14.2.5, respectively.

Table 10-5 Hypoglycaemia during pregnancy in mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint – MOTHER analysis set

Value	N	Events	Risk/Odds		95% CI	P-value
N= 1394						
Before propensity score matching						
Insulin Detemir	697	42	0.06/0.06			
Other Basal Insulin	697	63	0.09/0.10			
Insulin Detemir vs Other Basal Insulin						0.0419
Risk Difference				-0.030	(-0.058;-0.002)	
Odds Ratio				0.645	(0.430;0.968)	
N= 790						
After propensity score matching						
Insulin Detemir	395	35	0.09/0.10			
Other Basal Insulin	395	28	0.07/0.08			
Insulin Detemir vs Other Basal Insulin						0.3701
Risk Difference				0.018	(-0.021;0.056)	
Odds Ratio				1.274	(0.759;2.139)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

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Cross-reference: Modified from EOT Table 14.1.37

Pre-eclampsia during pregnancy

Summary of pre-eclampsia during pregnancy in patients in FAS_MOTHER analysis set, and MOTHER analysis set are presented in EOT Table 14.1.24 and EOT Table 14.1.25, respectively.

A statistical analysis of pre-eclampsia during pregnancy in patients, treated with insulin detemir compared to other basal insulins was performed before propensity score matching (crude model) in 1401 patients (700 patients on insulin detemir with 45 events, 701 patients on other basal insulins with 70 events) from MOTHER analysis set (Table 10-6). A significant difference was observed in the risk of pre-eclampsia in patients on insulin detemir treatment group compared to other basal insulin (p=0.0192), favouring insulin detemir. The RD between the two treatment groups was -0.036 (-0.064, -0.007)$_{95\%CI}$. The OR between the two treatment groups was 0.619 (0.419;0.915) $_{95\%CI}$.

Similar analysis was performed after propensity score matching in 796 patients (398 patients on insulin detemir with 31 events, 398 patients on other basal insulins with 38 events). No significant difference was observed in the risk of pre-eclampsia observed in patients on insulin detemir compared to other basal insulin (p=0.3853). The RD between the two treatment groups was 0.018 (-0.057;0.022)$_{95\%CI}$. The OR between the two treatment groups was 0.800 (0.487;1.314)$_{95\%CI}$.

Forest plots illustrating RD (crude and adjusted models) and OR (crude and adjusted models) of pre-eclampsia during pregnancy, in patients treated with insulin detemir compared to other basal insulins are presented in EOT Figures 14.2.4 and 14.2.5, respectively.

Table 10-6 Pre-eclampsia during pregnancy in mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - MOTHER analysis set

Value	N	Events	Risk/Odds		95% CI	P-value
N= 1401						
Before propensity score matching						
Insulin Detemir	700	45	0.06/0.07			
Other Basal Insulin	701	70	0.10/0.11			
Insulin Detemir vs Other Basal Insulin						0.0192
Risk Difference				-0.036	(-0.064;-0.007)	
Odds Ratio				0.619	(0.419;0.915)	
N= 796						
After propensity score matching						
Insulin Detemir	398	31	0.08/0.08			
Other Basal Insulin	398	38	0.10/0.11			
Insulin Detemir vs Other Basal Insulin						0.3853
Risk Difference				-0.018	(-0.057;0.022)	
Odds Ratio				0.800	(0.487;1.314)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

nis-primary/nn304-4016/current
18JUN2020:12:16:45 - t_param_mother_trt_anal.sas/t_preeclam_statanal_mother.txt

Cross-reference: Modified from EOT Table 14.1.38

Pregnancy outcome safety endpoints

Perinatal death

A statistical analysis of perinatal death among foetuses in FOETUS analysis set, was performed before propensity score matching in 1481 foetuses (741 foetuses of mothers on insulin detemir, with 6 events and 740 foetuses of mothers on other basal insulins, with 13 events, please refer section 10.4.1). No significant difference was observed in the risk of perinatal death in foetuses of mothers on insulin detemir compared to other basal insulins (p=0.1129). The RD between the two treatment groups was -0.009 (-0.021, 0.002)$_{95\%CI}$. The OR between the two treatment groups was 0.457 (0.173;1.208)$_{95\%CI}$. For further details refer to EOT Table 14.1.39.

A similar analysis was done after propensity score matching in 854 foetuses (427 foetuses of mothers on insulin detemir with 6 events and 427 foetuses of mothers on other basal insulins, with 5 events). No significant difference was observed in the risk of perinatal death in foetuses of mothers on insulin detemir compared to other basal insulins (p=0.7630). The RD between the two treatment groups was
0.002 (-0.015, 0.020)$_{95\%CI}$. The OR between the two treatment groups was 1.203 (0.364, 972)$_{95\%CI}$. For further details refer to EOT Table 14.1.39).

Forest plots illustrating RD (crude and adjusted) and OR (crude and adjusted models) of perinatal death among foetuses of mothers treated with insulin detemir compared to other basal insulins are presented in EOT Figures 14.2.4 and 14.2.5, respectively.

Neonatal death

A statistical analysis of neonatal death among offsprings in FOETUS analysis set, was performed before propensity score matching in 1449 offsprings (723 offsprings of mothers on insulin detemir, with 1 event and 726 offsprings of mothers on other basal insulins, with no event reported, please refer section 10.4.1). The RD between the two treatment groups was 0.001 (-0.001, 0.004)$_{95\%CI}$. For further details refer to EOT Table 14.1.40. Due to very low number of events it was not possible to do an adjusted RD analysis and OR could not be calculated.

Forest plot illustrating RD (crude model) of neonatal death among offsprings of mothers treated with insulin detemir compared to other basal insulins is presented in EOT Figure 14.2.5.

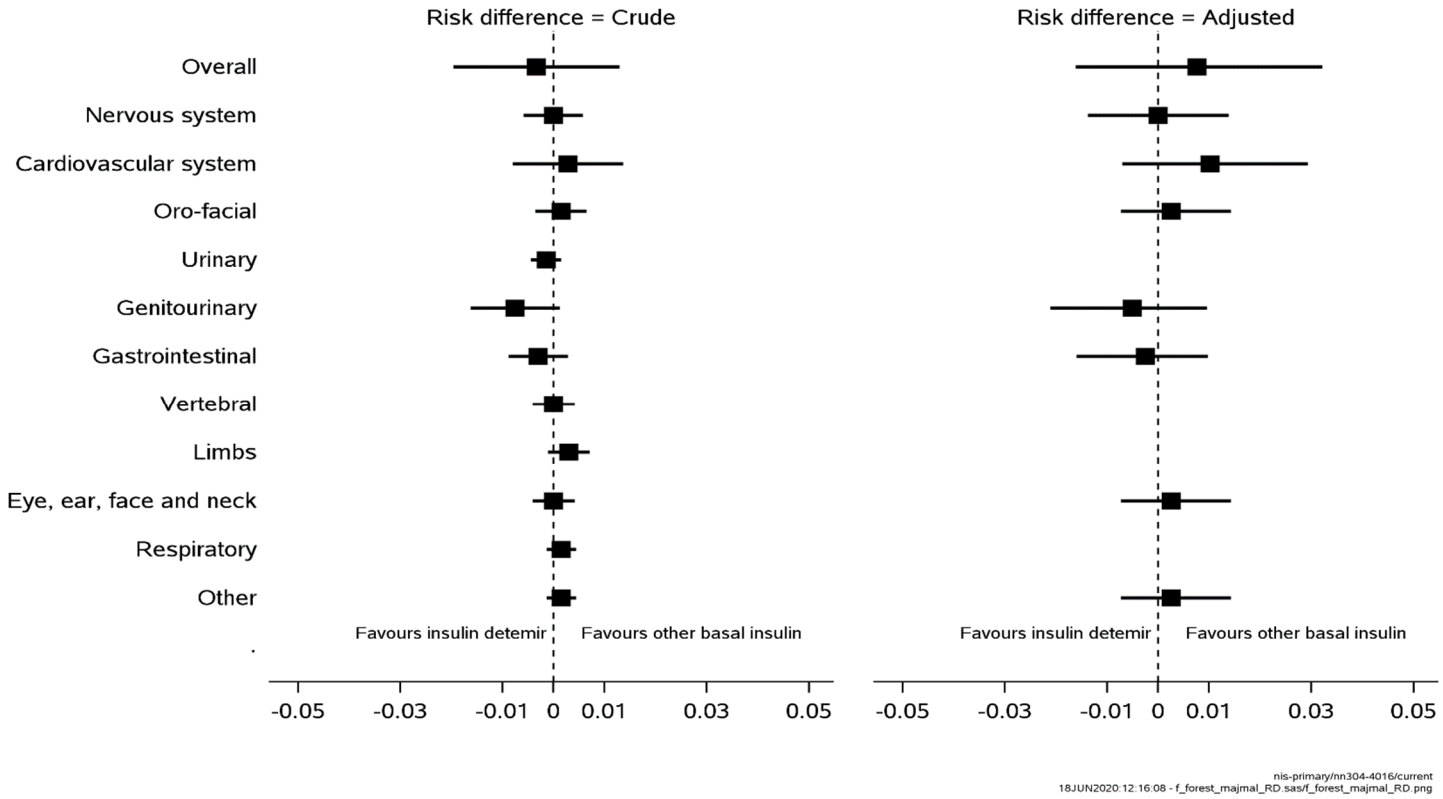
Major congenital malformations (overall and by organ)

A statistical analysis of major congenital malformations (overall and by organ) among liveborn infants from LIVEBORN analysis set, was performed before propensity score matching in 1368 infants (680 infants with 15 events born to mothers on insulin detemir 668 infants with 17 events born to mothers on other basal insulins, please refer section 10.4.1). Overall no significant difference was observed in the risk of major congenital malformations between the infants born to mothers on insulin detemir compared to other basal insulins (p=0.7232). The RD between the two

treatment groups was -0.003 (0.020, 0.013)$_{95\%CI}$. The OR between the two treatment groups was 0.864 (0.428, 1.744)$_{95\%CI}$. No significant difference was observed in the risk of major congenital malformations, by organ reported among liveborn infants born to mothers in the different basal insulin treatment groups from LIVEBORN analysis set. For further details refer to EOT Table 14.1.43)

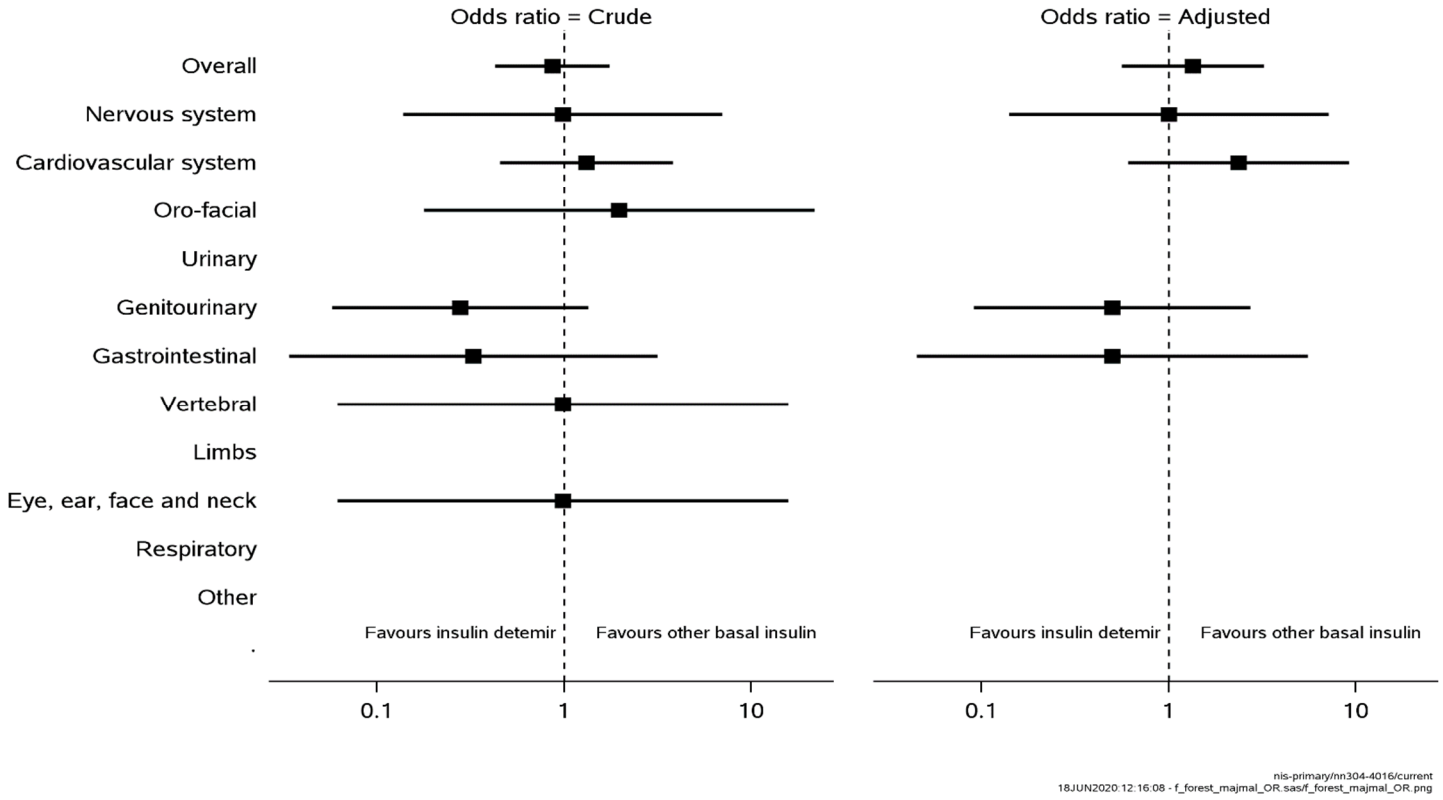
Similar analysis among liveborn infants from LIVEBORN analysis set, was performed after propensity score matching in 788 infants (394 infants born to mothers on insulin detemir, with 12 events and 394 infants born to mothers on other basal insulins, with 9 events). Overall no significant difference was observed in the risk of major congenital malformations between the infants born to mothers on insulin detemir compared to other basal insulins (p=0.5127). The RD between the two treatment groups was 0.008 (-0.016, 0.032)$_{95\%CI}$. The OR between the two treatment groups was 1.344 (0.560, 3.226)$_{95\%CI}$. No significant difference was observed in the risk of major congenital malformations, by organ among liveborn infants born to mothers in across treatment groups from LIVEBORN analysis set (see details in EOT Table 14.1.43).

Forest plots illustrating RD (crude and adjusted models) and OR (crude and adjusted models) of major congenital malformation among liveborn infants born to mothers treated with insulin detemir compared to other basal insulins overall and by organ are presented in Figure 4and Figure 5, respectively.



Cross-reference: EOT Figure 14.2.7

Figure 4 Risk difference of major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ -forest plot – LIVEBORN



Cross-reference: EOT Figure 14.2.6

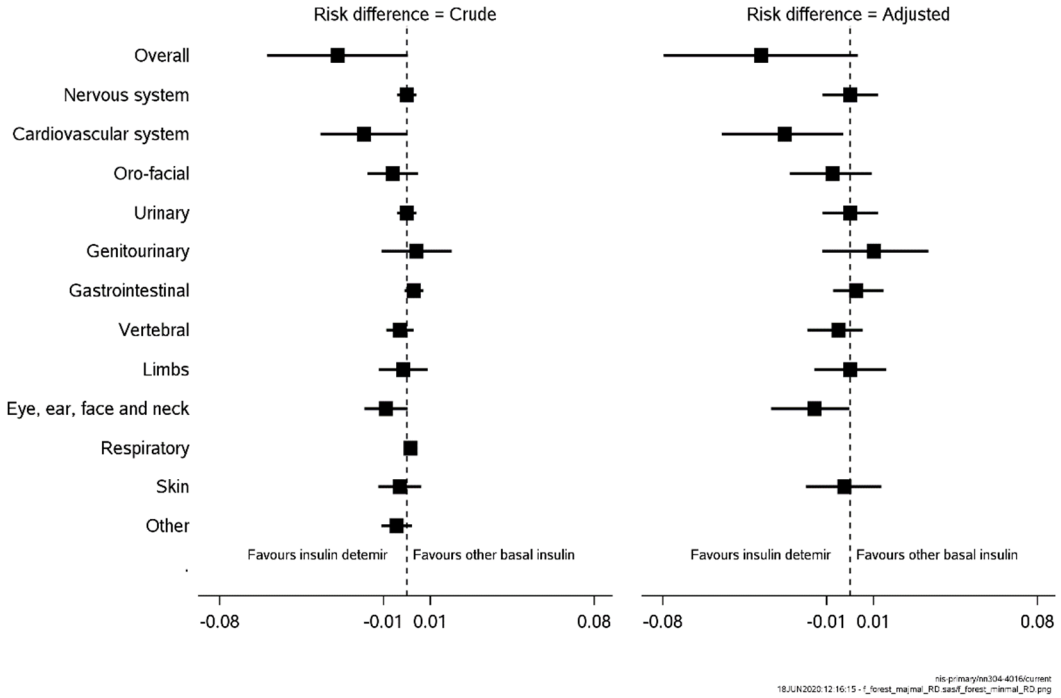
Figure 5 Odds ratio of major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ -forest plot – LIVEBORN

Minor congenital malformations (overall and by organ)

A statistical analysis of minor congenital malformations (overall and by organ) among liveborn infants from LIVEBORN analysis set, was performed before propensity score matching in 1348 infants (680 infants born to mothers on insulin detemir, with 49 events , 668 infants born to mothers on other basal insulins, with 68 events). Overall there was a tendency towards a lower risk of minor congenital malformations in the infants born to mothers in the insulin detemir treatment group compared to the other basal insulins treatment group, however the risk was not significant (p=0.0536). The absolute RD between the two treatment groups was -0.030 (-0.060, 0.000)$_{95\%CI}$. The OR between the two treatment groups was 0.685 (0.467, 1.006)$_{95\%CI}$. There was no significant difference in the risk of minor congenital malformations by organ among liveborn infants from LIVEBORN analysis set, born to mothers in each of the treatment groups (see details in EOT Table 14.1.44).

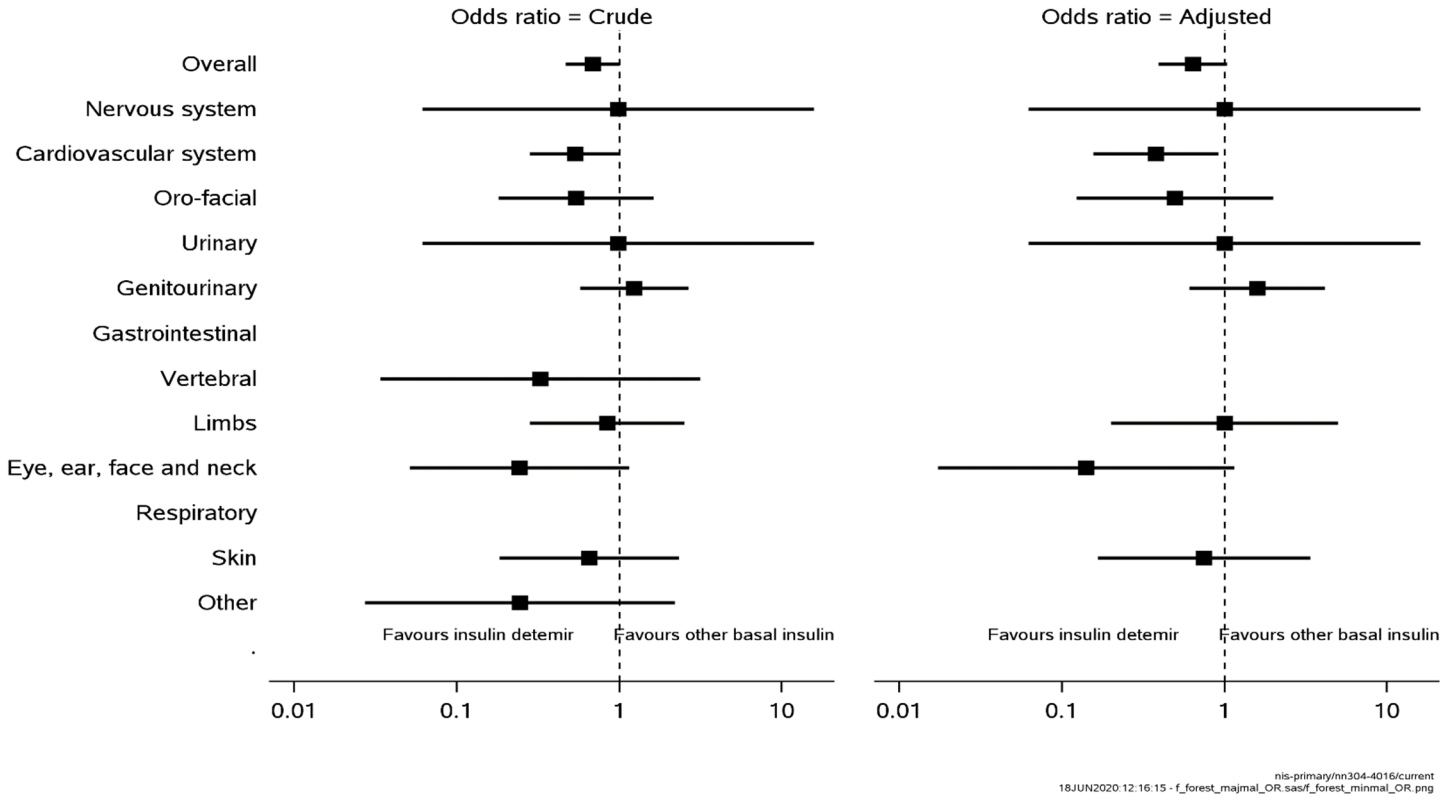
Similar analysis among liveborn infants from LIVEBORN analysis set, was performed after propensity score matching in 788 infants (394 infants born to mothers on insulin detemir, with 30 events and 394 infants born to mothers on other basal insulins, with 45 events). Overall there was a tendency towards a lower risk of minor congenital malformations in the infants born to mothers in the insulin detemir treatment group compared to the other basal insulins treatment group, however the risk was not significant (p=0.0588). The absolute RD between the two treatment groups was -0.038 (-0.080, 0.003)$_{95\%CI}$. The OR between the two treatment groups was 0.639 (0.394, 1.038)$_{95\%CI}$. There was no significant difference in the risk of minor congenital malformations, by organ among liveborn infants from LIVEBORN analysis set, born to mothers in each of the treatment groups (see details in EOT Table 14.1.44).

Forest plots illustrating RD (crude and adjusted models) and OR (crude and adjusted models) of minor congenital malformation among liveborn infants born to mothers treated with insulin detemir compared to other basal insulins overall and by organ are presented in Figure 6and Figure 7, respectively.



Cross-reference: EOT Figure 14.2.9

Figure 6 Risk difference of minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ -forest plot – LIVEBORN



Cross-reference: EOT Figure 14.2.8

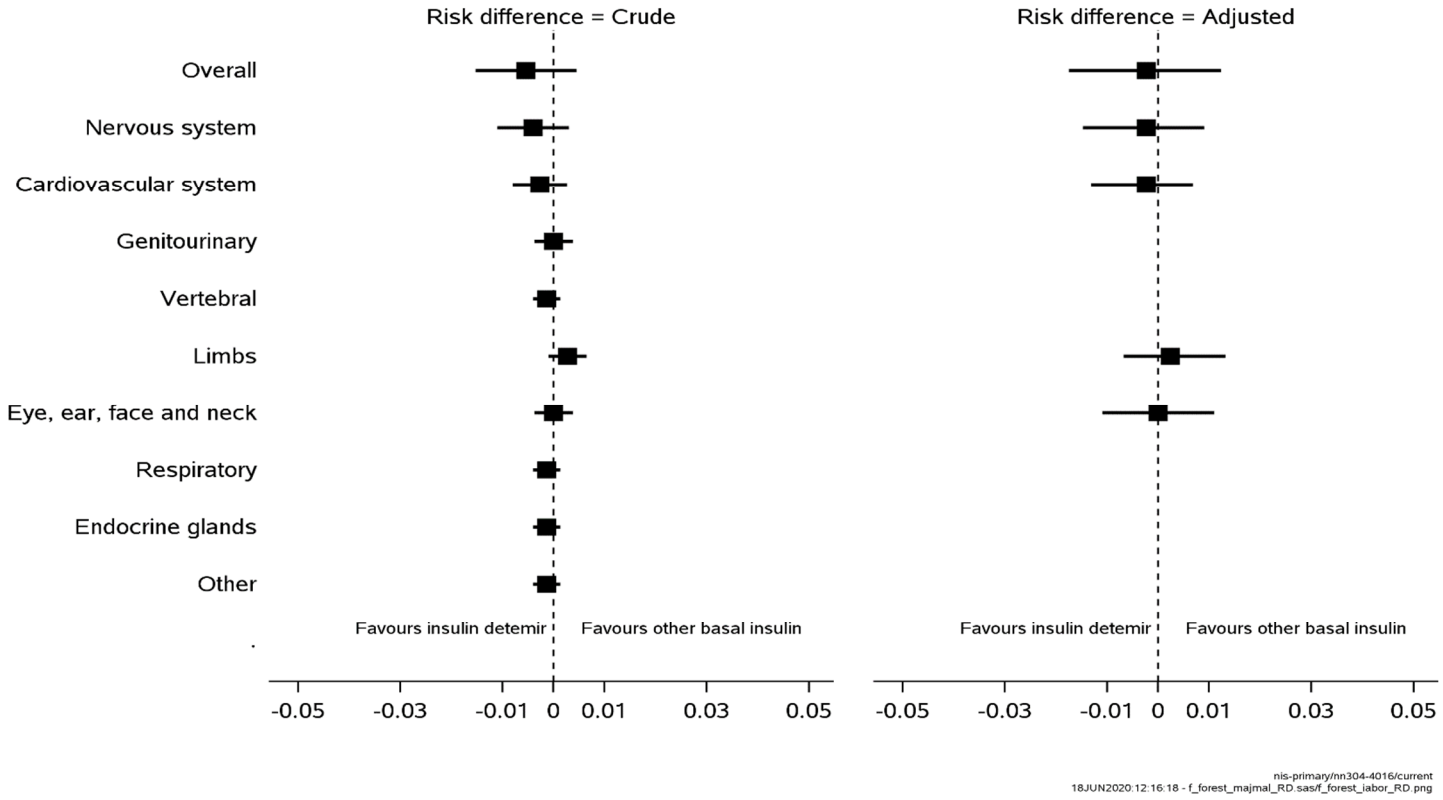
Figure 7 Odds ratio of minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ -forest plot – LIVEBORN

Induced abortions due to major congenital malformations (overall and by organ)

A statistical analysis of induced abortion due to major malformation (overall and organ wise) among foetus in FOETUS analysis set, was performed before propensity score matching in 1481 foetus (741 foetuses of mothers on insulin detemir, with 5 events and 740 foetuses of mothers on other basal insulins, with 9 events). Overall there was no significant difference in the risk of induced abortions due to major congenital malformations between the foetus of mothers on different basal insulins treatment group (p=0.2993). The RD between the two treatment groups was -0.005 (-0.015, 0.004)$_{95\%CI}$. The OR between the two treatment groups was 0.552 (0.184, 1.654)$_{95\%CI}$. There was no significant difference in the risk of induced abortions due to major congenital malformations, by organ reported among the foetus of mothers on different treatment groups (see details in EOT Table 14.1.41).

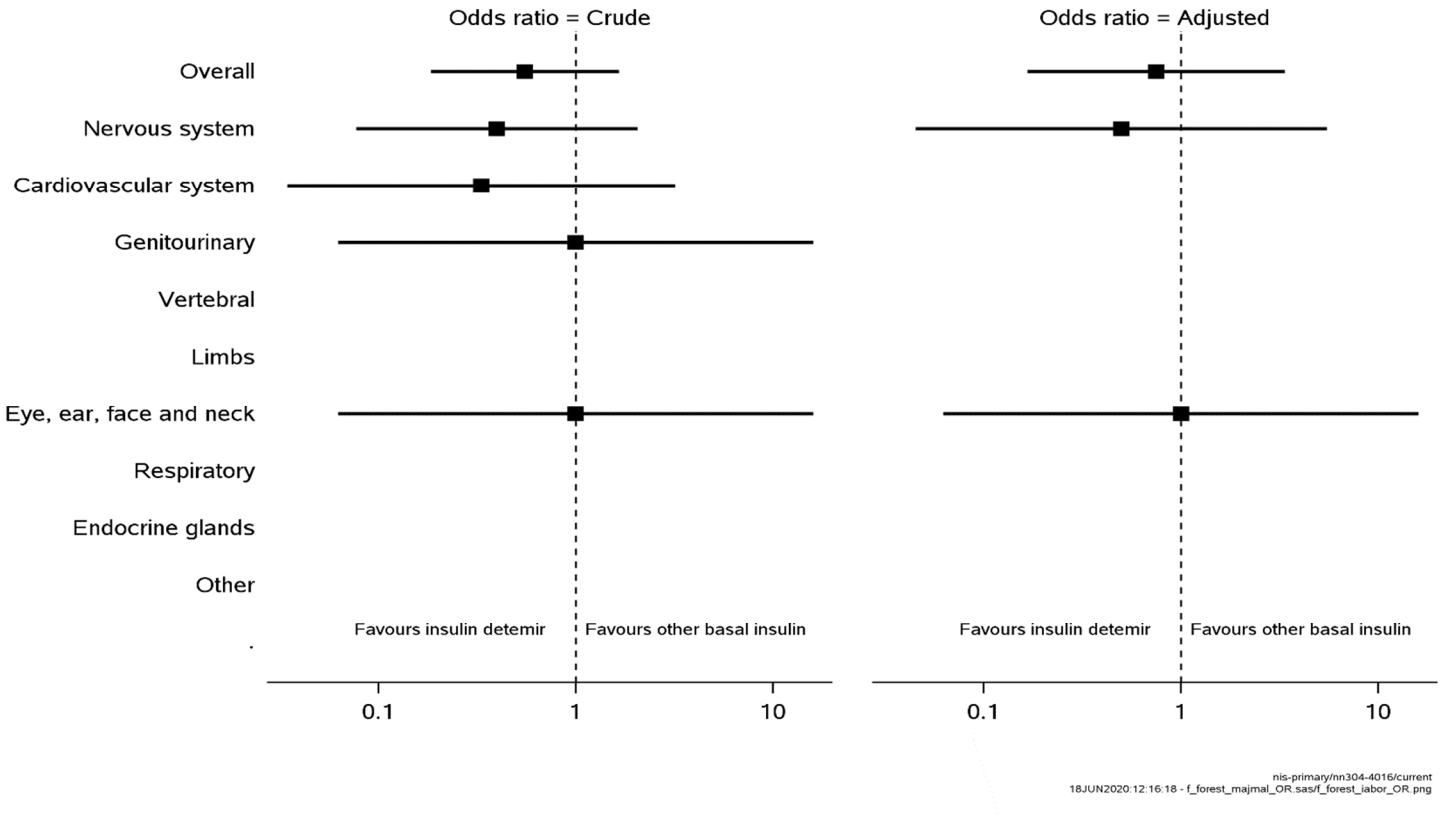
Similar analysis was done after propensity score matching in 854 patients (427 foetuses of mothers on insulin detemir, with 3 events, , and 427 foetuses of mothers on other basal insulins, with 4 events). Overall there was no significant difference in the risk of induced abortions due to major congenital malformations observed between the foetus of mothers on different insulins treatment group (p=0.7055). The RD between the two treatment groups was -0.002 (-0.018, 0.012)$_{95\%CI}$. The OR between the two treatment groups was 0.748 (0.166, 3.363)$_{95\%CI}$. There was no significant difference in the risk of induced abortions due to major congenital malformations, by organ among the foetus of mothers in different insulins treatment group (see details in EOT Table 14.1.41).

Forest plots illustrating RD (crude and adjusted models) and OR (crude and adjusted models) of induced abortions due to major malformation (overall and by organ) among foetus, in mothers treated with insulin detemir compared to other basal insulins are presented in Figure 8 and Figure 9, respectively.



Cross-reference: EOT Figure 14.2.11

Figure 8 Risk difference of induced abortion among foetus of mothers treated with basal insulin detemir compared to other basal insulins – forest plot – FOETUS analysis set



Cross-reference: EOT Figure 14.2.10

Figure 9 Odds ratio of induced abortion due to major malformations among foetus of mothers treated with basal insulin detemir compared to other basal insulins – forest plot – FOETUS analysis set

Spontaneous abortion

A statistical analysis for spontaneous abortion among foetus in FOETUS analysis set, was performed before propensity score matching in 1481 foetus (741 foetuses of mothers on insulin detemir, with 40 events, and 740 foetuses of mothers on other basal insulins, with 43 events). No significant difference in the risk of spontaneous abortions was observed among the foetus of mothers on different insulins treatment group (p=0.7363). The RD between the two treatment groups was -0.004 (-0.028, 0.019)$_{95\%CI}$. The OR between the two treatment groups was 0.925 (0.594, 1.441)$_{95\%CI}$ (see details in EOT Table 14.1.42).

Similar analysis was done after propensity score matching in 854 foetuses (427 foetuses of mothers on insulin detemir, with 20 events and 427 foetuses of mothers on other basal insulins, with 24 events). No significant difference in the risk of spontaneous abortions was observed among the foetus of mothers on different insulins treatment group (p=0.5465). The RD between the two treatment groups was -0.009 (-0.040, 0.021)$_{95\%CI}$. The OR between the two treatment groups was 0.825 (0.449, 1.517)$_{95\%CI}$ (see details in EOT Table 14.1.42).

Forest plots illustrating RD (crude and adjusted models) and OR (crude and adjusted models) of spontaneous abortions among foetus, of mothers treated with insulin detemir compared to other basal insulins are presented in EOT Figures 14.2.4 and 14.2.5, respectively

Foetal macrosomia

A statistical analysis for foetal macrosomia among liveborn infants in LIVEBORN analysis set was done before propensity score matching in 1350 infants (682 infants born to mothers on insulin detemir, with 125 events and 668 infants born to mothers on other basal insulins, with 118 events). No significant difference in the risk of foetal macrosomia was observed among the infants born to mothers on insulin detemir compared to other basal insulins (p=0.7771). The RD between the two treatment groups was -0.007 (-0.034, 0.048)$_{95\%CI}$. The OR between the two treatment groups was 1.046 (0.792, 1.381)$_{95\%CI}$ (see details in EOT Table 14.1.45).

Similar analysis was done after propensity score matching in 790 patients (395 patients born to mothers on insulin detemir, with 77 events and 395 patients born to mothers on other basal insulins with 64 events). No significant difference in the risk of foetal macrosomia was observed among the infants born to mothers on insulin detemir compared to other basal insulins (p=0.2334). The RD between the two treatment groups was 0.033 (-0.021, 0.086)$_{95\%CI}$. The OR between the two treatment groups was 1.252 (0.869, 1.805)$_{95\%CI}$ (see details in EOT Table 14.1.45).

Forest plots illustrating RD (crude and adjusted models) and OR (crude and adjusted models) of foetal macrosomia among foetus, of mothers treated with insulin detemir compared to other basal insulins are presented in EOT Figures 14.2.4 and 14.2.5, respectively

Large for gestational age

A statistical analysis for large for gestational age among liveborn infants in LIVEBORN analysis set, was performed before propensity score matching in 1285 infants (650 infants born to mothers on insulin detemir, with 305 events and 635 infants born to mothers on other basal insulins, with 326 events). No significant difference in the risk of large for gestational age was observed between the infants born to mothers on different basal insulin treatment groups (p=0.1184). The RD between the two treatment groups was -0.044 (-0.099, 0.010)$_{95\%CI}$. The OR between the two treatment groups was 0.838 (0.673, 1.043)$_{95\%CI}$ (EOT Table 14.1.46).

Similar analysis among liveborn infants from LIVEBORN analysis set, was performed after propensity score matching in 768 infants (384 infants born to mothers on insulin detemir, with 193 events and 384 infants born to mothers on other basal insulins, with 198 events). No significant difference in the risk of large for gestational age was observed between the infants born to mothers in the different basal insulin treatment groups (p=0.7086). The RD between the two treatment groups was -0.013 (-0.083, 0.057)$_{95\%CI}$. The OR between the two treatment groups was 0.949 (0.715, 1.260)$_{95\%CI}$ (EOT Table 14.1.46).

Forest plots illustrating RD (crude and adjusted models) and OR (crude and adjusted models) of large for gestational age among liveborn infants born to mothers treated with insulin detemir compared to other basal insulins are presented in EOT Figures 14.2.4 and 14.2.5, respectively.

Pre-term delivery

A statistical analysis for pre-term delivery among liveborn infants in LIVEBORN analysis set was done before propensity score matching in 1345 infants (681 infants born to mothers on insulin detemir, with 182 events and 664 infants born to mothers on other basal insulins, with 185 events). No significant difference in the risk of pre-term delivery was observed between the infants born to mothers in the different basal insulin treatment groups (p=0.6684). The RD between the two treatment groups was -0.011 (-0.059, 0.036)$_{95\%CI}$. The OR between the two treatment groups was 0.944 (0.743, 1.200)$_{95\%CI}$ (see details in EOT Table 14.1.47).

Similar analysis was done after propensity score matching in 788 infants (394 infants born to mothers on insulin detemir, with 111 events and 394 infants born to mothers on other basal insulins, with 104 events). No significant difference in the risk of pre-term delivery was observed between the infants born to mothers in the different basal insulin treatment groups (p=0.5788). The RD between the two treatment groups was 0.018 (-0.044, 0.080)$_{95\%CI}$. The OR between the two treatment groups was 1.094 (0.799, 1.497)$_{95\%CI}$ (see details in EOT Table 14.1.47).

Forest plots illustrating RD (crude and adjusted models) and OR (crude and adjusted models) of pre-term delivery among liveborn infants born to mothers treated with insulin detemir compared to other basal insulins are presented in EOT Figures 14.2.4 and 14.2.5, respectively.

10.4.2.3 Infant safety endpoints

Height at the age of 1 year

A statistical analysis of height (cm) of infants at 1 year of age among 1139 infants (581 infants born to mothers on insulin detemir, 588 infants born to mothers on other basal insulins) in INFANT analysis set is presented in Table 10-7. The estimated height (cm) evaluated by crude model, was 76.52 cm in infants born to mothers on insulin detemir compared to 76.34 cm in infants born to mothers on other basal insulins. The treatment difference between the two treatment groups was 0.18 (-0.34, 0.71)$_{95\%CI}$, p= 0.4970. The estimated height evaluated by adjusted model, was 76.45 cm in infants born to mothers on insulin detemir compared to 76.60 cm in infants born to mothers on other basal insulins. The difference between the two treatment groups was -0.16 (-0.76, 0.45)$_{95\%CI}$, p= 0.6127.

The mean observed height of infants in INFANT analysis set, born to mothers on insulin detemir, on other basal insulins and on no basal insulins, at 1-year visit was 76.52 (4.76) cm, 76.34 (4.28) cm and 76.43 (4.53) cm, respectively.(EOT Table 14.1.23).

Weight at the age of 1 year

A statistical analysis of weight (grams) of infants at 1 year of age among 1175 infants (593 infants born to mothers on insulin detemir and 582 infants born to mothers on other basal insulins) in INFANT analysis set is presented in Table 10-7. The estimated weight (grams) evaluated by crude model, was 10103.66 grams in infants born to mothers on insulin detemir compared to 9975.69 grams estimated weight in infants born to mothers on other basal insulins. The difference between the two treatment groups was 127.97 (-25.15, 281.10)$_{95\%CI}$, p= 0.1013. The estimated weight evaluated by adjusted model, was 10046.30 grams in infants born to mothers on insulin detemir compared to 10069.52 grams estimated weight in infants born to mothers on other basal insulins. The difference between the two treatment groups was -23.22 (-201.75, 155.32)$_{95\%CI}$, p=0.80.

The mean observed weight of infants in INFANT analysis set, born to mothers on insulin detemir, on other basal insulins and on no basal insulins, at 1-year visit was 10103.66 (1318.76) grams, 9975.69 (1356.47) grams and 10040.28 (1338.53) grams, respectively.(EOT Table 14.1.23).

Table 10-7 Height and weight at 1 year of age among infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - INFANT analysis set

	N	Estimate	SE	95% CI	P-value
Height (cm)					
Number of observations in the analysis = 1139					
Crude model					
Insulin detemir	581	76.52			
Other basal insulin	558	76.34			
Insulin detemir - Other basal insulin		0.18	0.27	[-0.34 , 0.71]	0.4970
Adjusted model					
Insulin detemir	581	76.45			
Other basal insulin	558	76.60			
Insulin detemir - Other basal insulin		-0.16	0.31	[-0.76 , 0.45]	0.6127
Weight (gram)					
Number of observations in the analysis = 1175					
Crude model					
Insulin detemir	593	10103.66			
Other basal insulin	582	9975.69			
Insulin detemir - Other basal insulin		127.97	78.05	[-25.15 , 281.10]	0.1013
Adjusted model					
Insulin detemir	593	10046.30			
Other basal insulin	582	10069.52			
Insulin detemir - Other basal insulin		-23.22	90.99	[-201.75 , 155.32]	0.7986

Covariates used for crude model are basal insulin treatment group and that for adjusted model are country, basal insulin treatment group, age of mother, type of diabetes of mother, previous lactation, educational level of mother, N: Number of patients, Regression crude and fully adjusted models are performed

nis-primary/nn304-4016/20200312_nsr_er
18JUN2020:12:16:29 - t_hei_wei_fts.sas/t_hei_wei_fts.txt

Cross-reference: EOT Table 14.1.49

DM status

A statistical analysis of the status of DM in infants at 1 year of age among infants in INFANT analysis set, was performed before propensity score matching in 1259 infants (632 infants born to mothers on insulin detemir, with 2 events and 627 infants born to mothers on other basal insulins, with 2 events). No significant difference in the risk of DM was observed between the infants born to mothers on insulin detemir treatment compared to other basal insulins (p=1.000). The RD between the two treatment groups was -0.000 (-0.006;0.006)$_{95\%CI}$. The OR between the two treatment groups was 0.992 (0.139;7.065).$_{95\%CI}$ (see details in Table 10-8). Similar analysis was done after propensity score matching in 736 infants (368 infants born to mothers on insulin detemir, with 2 events and 368 infants born to mothers on other basal insulins, with 2 events). No significant difference in the risk of DM was observed between the infants born to mothers on insulin detemir compared to other basal insulins (p=1.000). The RD between 2 different treatment groups was 0.000 (-0.015, 0.015)$_{95\%CI}$. The OR between 2 different treatment groups was 1.000 (0.140, 7.137)$_{95\%CI}$ (see details in Table 10-8).

Changes (progression/regression) of major congenital malformations

A summary of changes of major congenital malformations in infants from INFANT analysis set 1268 infants (638 infants born to mothers on insulin detemir and 630 infants born to mothers on other basal insulins at enrolment), before propensity score matching is presented in Table 10-9.

Of the 622 infants born to the mothers on insulin detemir, 611 infants had no major congenital malformations, 7 infants had no change, 2 infants had progression and 2 infants had regression in major congenital malformations. Of the 609 infants born to the mothers on other basal insulins treatment group, 594 infants had no major congenital malformations, 10 infants had no change, and 5 infants were reported with regression in major congenital malformations.

A similar analysis in 736 infants from INFANT analysis set (368 infants born to mother on insulin detemir and 368 infants born to mothers on other insulins) after propensity score matching is presented in Table 10-9. Of the 353 infants born to the mothers on insulin detemir, 344 infants had no major congenital malformations, 5 infants had no change, 2 infants had progression and 2 infants had regression in major congenital malformations. Out of a total of 355 infants born to the mothers on other basal insulins treatment group, 345 infants had no major congenital malformations, 6 infants had no change, and 4 infants were reported with regression in major congenital malformations (Table 10-9).

Table 10-8 Diabetes at 1 year of age among infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - INFANT analysis set

Value	N	Events	Risk/Odds		95% CI	P-value
N= 1259						
Before propensity score matching						
Insulin Detemir	632	2	0.0032/0.0032			
Other Basal Insulin	627	2	0.0032/0.0032			
Insulin Detemir vs Other Basal Insulin						1.0000
Risk Difference				-0.000	(-0.006;0.006)	
Odds Ratio				0.992	(0.139;7.065)	
N= 736						
After propensity score matching						
Insulin Detemir	368	2	0.0054/0.0055			
Other Basal Insulin	368	2	0.0054/0.0055			
Insulin Detemir vs Other Basal Insulin						1.0000
Risk Difference				0.000	(-0.015;0.015)	
Odds Ratio				1.000	(0.140;7.137)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

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18JUN2020:12:16:39 - t_param_infant_trt_anal.sas/t_diabetes1yr_statanal_infant.txt

Cross-reference: EOT Table 14.1.48

Table 10-9 Changes of major congenital malformations by basal insulin treatment group at enrolment before and after propensity score matching - summary - INFANT analysis set

	Before propensity score matching (N=1268)				After propensity score matching (N=736)			
	Insulin Detemir (N=638)		Other Basal Insulin (N=630)		Insulin Detemir (N=368)		Other Basal Insulin (N=368)	
Changes of major congenital malformation								
n	622		609		353		355	
No change	7	(1.1)	10	(1.6)	5	(1.4)	6	(1.7)
Progression	2	(0.3)			2	(0.6)		
Regression	2	(0.3)	5	(0.8)	2	(0.6)	4	(1.1)
No major congenital malformation	611	(98.2)	594	(97.5)	344	(97.5)	345	(97.2)

N: Number of patients, SD: Standard deviation
Percentages are based on total number of patients in the analysis set with information.

nis-primary/nn304-4016/current
18JUN2020:12:16:33 - t_maj_conj_mal.sas/t_maj_conj_mal.txt
Cross-reference: EOT Table 14.1.54

10.4.3 Summary of main results

No difference between treatment with insulin detemir versus other basal insulins were observed with respect to the primary endpoint (pregnancy outcomes not resulting in major congenital malformation, perinatal death, neonatal death).

- 97% insulin detemir vs 95% other basal insulin, RD = 0.015 (-0.01, 0.04)$_{95\% \text{ CI}}$

No difference between treatment groups were observed for any other adverse pregnancy outcomes or glycaemic control during pregnancy. A non-significant tendency towards lower risk of minor malformation was observed in children born to mothers on insulin detemir compared to other basal insulins. A very low number of neonatal deaths were observed, hence it was not possible to do an adjusted analysis. A significant difference was observed in the risk of major hypoglycaemia and pre-eclampsia in crude analyses for the patients on insulin detemir compared to other basal insulin, favouring insulin detemir, however no difference was observed in the adjusted analyses.

No differences between treatment groups were observed in growth or presence of diabetes of the infant at 1-year of age.

10.5 Other analyses

Not applicable for this study.

10.6 Adverse events/adverse drug reactions

10.6.1 Adverse drug reactions by SOC and PT

ADRs by system organ class (SOC) and preferred terms (PT), in FAS_MOTHER set are presented in Table 10-10. A total of 267 ADRs were reported in 241 out of 2373 patients (67 ADRs in 64 patients on insulin detemir, 98 ADRs in 92 patients on other basal insulins, and 102 ADRs in 85 patients on no basal insulin at enrolment) during the study. Most of the ADRs were within the SOC of Metabolism and nutrition disorders with Hypoglycaemia as the most frequently reported PT (173 patients, 7.3%). A summary of ADRs in FAS_MOTHER analysis set, by basal insulin treatment group at enrolment is presented in EOT Table 14.1.56.

ADRs by SOC and PT, in FAS_FOETUS set are presented in Table 10-11. A total of 91 ADRs were reported in 83 out of 2396 foetus (30 ADRs in 26 foetuses of mothers on insulin detemir, 24 ADRs in 24 foetuses of mothers on other basal insulins, and 37 ADRs in 33 foetuses of mothers on no basal insulin at enrolment), during the study. Most of the ADRs were within the SOC of Metabolism and nutrition disorders with Hypoglycaemia neonatal as the most frequently reported PT (56 patients, 2.3%) in this SOC. A summary of ADRs in FAS_FOETUS analysis set, by basal insulin treatment group at enrolment is presented in EOT Table 14.1.56.

Table 10-10 ADR categorised by System Organ Class and Preferred Term among mothers– FAS_MOTHER

System Organ Class Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Total number of patients	764	828	781	2373
Total number of patients with events	64 (8.4)	92 (11.1)	85 (10.9)	241 (10.2)
Blood and lymphatic system disorders	1 (0.1)			1 (0.1)
Splenic haematoma	1 (0.1)			1 (0.1)
Cardiac disorders		1 (0.1)		1 (0.1)
Palpitations		1 (0.1)		1 (0.1)
Eye disorders			2 (0.3)	2 (0.1)
Diabetic retinopathy			1 (0.1)	1 (0.1)
Vision blurred			1 (0.1)	1 (0.1)
Gastrointestinal disorders		2 (0.2)	2 (0.3)	4 (0.2)
Vomiting		2 (0.2)	2 (0.3)	4 (0.2)
General disorders and administration site conditions	2 (0.3)	1 (0.1)	4 (0.5)	7 (0.3)
Injection site eczema	1 (0.1)			1 (0.1)
Injection site erythema			1 (0.1)	1 (0.1)
Injection site oedema		1 (0.1)		1 (0.1)
Injection site pain	1 (0.1)		1 (0.1)	2 (0.1)
Macrosomia			1 (0.1)	1 (0.1)
Malaise			1 (0.1)	1 (0.1)
Hepatobiliary disorders	1 (0.1)			1 (0.1)
Hepatic haematoma	1 (0.1)			1 (0.1)

N: Number of patients with one or more events, %: percentage of patients with one or more events, ADR: Adverse drug reaction
MedDRA version - 22.1.

ADR categorised by System Organ Class and Preferred Term among mothers- FAS_MOTHER

System Organ Class Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Infections and infestations	1 (0.1)		2 (0.3)	3 (0.1)
Dermatophytosis			1 (0.1)	1 (0.1)
Herpes simplex otitis externa	1 (0.1)			1 (0.1)
Upper respiratory tract infection			1 (0.1)	1 (0.1)
Injury, poisoning and procedural complications	1 (0.1)			1 (0.1)
Femoral neck fracture	1 (0.1)			1 (0.1)
Foot fracture	1 (0.1)			1 (0.1)
Hand fracture	1 (0.1)			1 (0.1)
Rib fracture	1 (0.1)			1 (0.1)
Investigations	2 (0.3)	2 (0.2)	3 (0.4)	7 (0.3)
Blood glucose fluctuation	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Blood ketone body present		1 (0.1)		1 (0.1)
Blood pressure increased	1 (0.1)			1 (0.1)
Urine ketone body present			1 (0.1)	1 (0.1)
Metabolism and nutrition disorders	54 (7.1)	80 (9.7)	70 (9.0)	204 (8.6)
Decreased insulin requirement	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
Diabetes mellitus			1 (0.1)	1 (0.1)
Diabetes mellitus inadequate control	3 (0.4)	14 (1.7)	17 (2.2)	34 (1.4)
Diabetic ketoacidosis	4 (0.5)		3 (0.4)	7 (0.3)
Diabetic metabolic decompensation			1 (0.1)	1 (0.1)
Hyperglycaemia	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
Hypoglycaemia	48 (6.3)	69 (8.3)	56 (7.2)	173 (7.3)
Hypoglycaemia unawareness	1 (0.1)			1 (0.1)
Ketosis		1 (0.1)		1 (0.1)
Nervous system disorders	1 (0.1)	3 (0.4)	5 (0.6)	9 (0.4)

N: Number of patients with one or more events, %: percentage of patients with one or more events, ADR: Adverse drug reaction
MedDRA version - 22.1.

ADR categorised by System Organ Class and Preferred Term among mothers- FAS_MOTHER

System Organ Class Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Headache		1 (0.1)	1 (0.1)	2 (0.1)
Hypoaesthesia			1 (0.1)	1 (0.1)
Hypoglycaemic coma			1 (0.1)	1 (0.1)
Hypoglycaemic seizure		1 (0.1)	1 (0.1)	2 (0.1)
Hypoglycaemic unconsciousness	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Tremor			1 (0.1)	1 (0.1)
Pregnancy, puerperium and perinatal conditions	2 (0.3)	4 (0.5)	9 (1.2)	15 (0.6)
Abortion		1 (0.1)		1 (0.1)
Foetal disorder			2 (0.3)	2 (0.1)
Foetal macrosomia	2 (0.3)		4 (0.5)	6 (0.3)
HELLP syndrome		1 (0.1)		1 (0.1)
Large for dates baby			2 (0.3)	2 (0.1)
Polyhydramnios			1 (0.1)	1 (0.1)
Pre-eclampsia		2 (0.2)	2 (0.3)	4 (0.2)
Renal and urinary disorders	1 (0.1)		1 (0.1)	2 (0.1)
Ketonuria			1 (0.1)	1 (0.1)
Polyuria	1 (0.1)			1 (0.1)
Reproductive system and breast disorders			1 (0.1)	1 (0.1)
Coital bleeding			1 (0.1)	1 (0.1)
Skin and subcutaneous tissue disorders	1 (0.1)	3 (0.4)		4 (0.2)
Lipodystrophy acquired		1 (0.1)		1 (0.1)
Lipohypertrophy	1 (0.1)	1 (0.1)		2 (0.1)
Rash		1 (0.1)		1 (0.1)
Surgical and medical procedures		1 (0.1)	3 (0.4)	4 (0.2)

N: Number of patients with one or more events, %: percentage of patients with one or more events, ADR: Adverse drug reaction
MedDRA version - 22.1.

ADR categorised by System Organ Class and Preferred Term among mothers- FAS_MOTHER

System Organ Class Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Diabetes mellitus management		1 (0.1)		1 (0.1)
Labour induction			3 (0.4)	3 (0.1)
Vascular disorders		1 (0.1)		1 (0.1)
Hypertension		1 (0.1)		1 (0.1)

N: Number of patients with one or more events, %: percentage of patients with one or more events, ADR: Adverse drug reaction
MedDRA version - 22.1.

Cross-reference: EOT Table 14.1.52

Table 10-11 ADR categorised by System Organ Class and Preferred Term among foetus/infants – FAS_FOETUS

System Organ Class Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Total number of patients	773	828	795	2396
Total number of patients with events	26 (3.4)	24 (2.9)	33 (4.2)	83 (3.5)
Congenital, familial and genetic disorders	1 (0.1)	1 (0.1)		2 (0.1)
Cleft palate		1 (0.1)		1 (0.1)
Patent ductus arteriosus	1 (0.1)			1 (0.1)
General disorders and administration site conditions			3 (0.4)	3 (0.1)
Macrosomia			3 (0.4)	3 (0.1)
Infections and infestations		1 (0.1)		1 (0.1)
Oral fungal infection		1 (0.1)		1 (0.1)
Injury, poisoning and procedural complications			1 (0.1)	1 (0.1)
Skull fracture			1 (0.1)	1 (0.1)
Metabolism and nutrition disorders	24 (3.1)	21 (2.5)	29 (3.6)	74 (3.1)
Hyperinsulinaemic hypoglycaemia	1 (0.1)			1 (0.1)
Hypoglycaemia	7 (0.9)	3 (0.4)	7 (0.9)	17 (0.7)
Hypoglycaemia neonatal	16 (2.1)	18 (2.2)	22 (2.8)	56 (2.3)
Pregnancy, puerperium and perinatal conditions	2 (0.3)		3 (0.4)	5 (0.2)
Jaundice neonatal	1 (0.1)			1 (0.1)
Large for dates baby	1 (0.1)			1 (0.1)
Premature baby			3 (0.4)	3 (0.1)
Respiratory, thoracic and mediastinal disorders	3 (0.4)	1 (0.1)	1 (0.1)	5 (0.2)

N: Number of patients with one or more events, %: percentage of patients with one or more events, ADR: Adverse drug reaction
MedDRA version - 22.1.

ADR categorised by System Organ Class and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Neonatal respiratory distress syndrome			1 (0.1)	1 (0.1)
Respiratory distress	2 (0.3)	1 (0.1)		3 (0.1)
Tachypnoea	1 (0.1)			1 (0.1)

N: Number of patients with one or more events, %: percentage of patients with one or more events, ADR: Adverse drug reaction
MedDRA version - 22.1.

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Cross-reference: EOT Table 14.1.53

10.6.2 Deaths

One (1) patient in FAS_MOTHER analysis set died during the observation period. The patient was on other basal insulin. The patient experienced an event of cardiac arrest, not related to treatment, with a fatal outcome (refer to Listings 16.2.7.1 and 16.2.7.3 and Appendix 16.3.1).

A total of 31 perinatal death (6 deaths in patients on insulin detemir, 13 deaths in patients on other basal insulin and 12 deaths in patients on no basal insulin group) and 1 event leading to neonatal death (in a patient on insulin detemir) in FAS_FOETUS analysis set (see details in EOT Table 14.1.18) were reported during the observation period (the serious adverse events resulting in perinatal deaths were recorded either in the mother AE form or in the infant AE form). The SAEs leading to perinatal deaths and neonatal deaths were evaluated as unlikely related to the treatment (refer to EOT Listing 16.2.7.4).

A total of 193 abortions [122 spontaneous abortions (42 events in mothers on insulin detemir, 46 events in mothers on other basal insulin and 34 events in mothers on no basal insulin) and 71 induced abortions (20 events in mothers on insulin detemir, 21 events in mothers on other basal insulin and 30 events in mothers on no basal insulin), see details in EOT Table 14.1.18] in FAS_FOETUS analysis set were reported during the observation period.

For details on perinatal and neonatal deaths in foetus of mothers in each treatment group please refer section 10.4.2.

10.6.3 Other serious adverse events/adverse drug reactions

A summary of SAEs in mothers and infants, along with the severity and outcome of event is provided in EOT Listing 16.2.7.2.

SAEs by SOC and PT, reported in FAS_MOTHER set are presented in EOT Table 14.1.50. A total of 1664 SAEs were reported in 1097 out of 2373 patients (431 SAEs in 282 patients on insulin detemir, 577 SAEs in 392 patients on other basal insulins, and 656 SAEs in 423 patients on no basal insulin at enrolment) during the study. Highest number of SAEs were reported within the SOC Pregnancy, puerperium and perinatal conditions, followed by Infections and infestations. The most commonly reported SAE by PT in SOC Pregnancy, puerperium and perinatal conditions was Pre-eclampsia and in SOC Infections and infestations was Gastroenteritis in each treatment group. A summary of SAEs in FAS_MOTHER analysis set, by basal insulin treatment group at enrolment is presented in EOT Table 14.1.55.

SAEs by SOC and PT, in FAS_FOETUS set are presented in EOT Table 14.1.51. A total of 1530 SAEs were reported in 886 out of 2396 foetuses (391 SAEs in 237 foetuses of mothers on insulin detemir, 576 SAEs in 328 foetuses of mothers on other basal insulins, and 576 SAEs in 321 foetuses of mothers on no basal insulin at enrolment) during the study. Most of the SAEs were within the SOC of ‘Respiratory, thoracic and mediastinal disorders’. The most commonly reported

SAE by PT was 'Premature baby' (reported in 178 patients). A summary of SAEs in FAS_FOETUS analysis set, by basal insulin treatment group at enrolment is presented in EOT Table 14.1.55.

10.6.4 Other significant adverse events/adverse drug reactions

No other significant adverse event/ adverse drug reaction was observed during the study.

10.6.5 Other observations related to safety

No other safety information was collected during the study.

10.6.6 Pregnancy

Please refer section10.4 for details.

10.6.7 Summary of adverse events/adverse drug reactions

All ADRs and SAEs in pregnant women participating in the study, as well as in their off-spring until 1-year of age, were collected systematically.

During the observation period a total of 67 ADRs in 764 mothers on insulin detemir, 98 ADRs in 828 mothers on other basal insulins, and 102 ADRs in 781 mothers on no basal insulin were reported.

A total of 431 SAEs in 764 mothers on insulin detemir, 577 SAEs in 828 mothers on other basal insulins, and 656 SAEs 781 mothers on no basal insulin were reported in this study.

During the 12-month post-delivery observation period, a total of 30 ADRs in 773 foetus/infants of mothers on insulin detemir, 24 ADRs in 828 foetus/infants of mothers on other basal insulins, and 37 ADRs in 795 foetus/infants of mothers on no basal insulin were reported.

A total of 391 SAEs in 773 foetus/infants of mothers on insulin detemir, 576 SAEs in 828 foetus/infants of mothers on other basal insulins, and 563 SAEs in 795 foetus/infants of mothers on no basal insulin were reported in this study.

Most of the ADRs in mothers and foetus/ infants were within the SOC of 'Metabolism and nutrition disorders' with 'Hypoglycaemia' being the most reported PT in mothers and 'Hypoglycaemia neonatal' being the most reported PT in infants/foetus in each treatment group.

One patient (1) on other basal insulin died of cardiac arrest during the study. The event was assessed 'not related' to the study treatment.

A total of 31 events leading to perinatal death and 1 event leading to neonatal death were reported during the observation period.

11 Discussion

The women with pre-existing diabetes are at increased risk of pregnancy complications like congenital malformations, perinatal death, neonatal death, preterm delivery and foetal overgrowth. The use of insulin analogues, insulin pumps and continuous glucose monitoring (CGM) might help improve glycaemic control in pregnancy. However, data on the effect of basal insulin analogues on risk of congenital malformations, neonatal and perinatal death are limited.

As no long-term prospective epidemiological studies examining safety of different insulin treatment regimens in pregnant women with DM and pregnancy outcomes have been conducted, this study was carried out to monitor the safety of the use of insulin detemir and other basal injectable antidiabetic treatment regimens in pregnant women during the gestational period. This study also monitored their infants at 1-month and at 1-year of age.

11.1 Key results

No difference between treatment with insulin detemir versus other basal insulins were observed with respect to the primary endpoint (none of the following: major congenital malformation, perinatal death, neonatal death.

- Primary analysis of primary endpoint: RD = 0.015 $(-0.01, 0.04)_{95\% \text{ CI.}}$

No difference between treatment groups (insulin detemir versus other basal insulin) were observed for any other adverse pregnancy outcomes or glycamic control during pregnancy.

No differences between treatment groups (insulin detemir versus other basal insulin) were observed in growth or presence of diabetes of the infant at 1 year of age

Overall, treatment with insulin detemir was not associated with increased risk, when compared to treatment with other basal insulin during pregnancy, in women with pre-existing diabetes.

11.2 Strengths and Limitations

This study was carried out with a major objective of monitoring and assessing the safety of insulin detemir in women with pre-existing diabetes during pregnancy. The study had some strengths:

- The protocol and progress reports were approved by EMA.
- The real world data was collected for a large sample size.
- The study had very broad inclusion criteria and few exclusion criteria and patients from many nationalities were enrolled in the study.
- Many covariates were applied for the confounder control
- The study collected longitudinal data from early pregnancy to the age of 1-year of the infant.

However this study exhibited some potential factors of limitation:

- The study was not a randomised study.
- Recruitment of women was done at selected specialised diabetes clinics.
- Adverse pregnancy outcomes in early pregnancy may have been missed.
- Lower number of events observed for some endpoints.

11.3 Interpretation

In this large prospective cohort study with broad inclusion criteria no difference in the predefined major outcome of severe pregnancy outcome was detected among pregnant women receiving insulin detemir or other basal insulins. In addition, glycemic control and a large number of other safety parameters for the mother and child up to one year of age, were similar in the two groups.

11.4 Generalisability

The present large prospective cohort study with broad inclusion criteria was conducted in pregnant women with T1DM or T2DM from 17 countries. This real world study cohort makes the finding generalizable to the world-wide population of pregnant women with pre-existing diabetes.

12 Other information

Not applicable for this trial.

13 Conclusion

In this large scale prospective cohort study with broad inclusion criteria no difference in the predefined major outcome of severe pregnancy outcome was detected among pregnant women with type 1 or type 2 diabetes receiving insulin detemir or other basal insulins. In addition, glycaemic control and a large number of other safety parameters for the mother and child up to one year of age, were similar in the two groups.

The results indicate that insulin detemir is not associated with increased risk, when compared to treatment with other basal insulin during pregnancy, in women with pre-existing diabetes.

14.1 Demographics and other assessments

14.1.1 Invitation and participation - country - Enrolment log

	Invited N	Enrolled N	Participation %
Total	2601	2446	94.0
Croatia	324	311	96.0
Denmark	643	627	97.5
Finland	155	150	96.8
France	178	165	92.7
Germany	35	35	100.0
Greece	11	11	100.0
Ireland	74	74	100.0
Israel	215	215	100.0
Italy	70	70	100.0
Malaysia	27	27	100.0
Netherlands	91	70	76.9
Norway	47	45	95.7
Poland	130	127	97.7
Portugal	21	19	90.5
Romania	26	26	100.0
Spain	185	168	90.8
United Kingdom	369	306	82.9

N: Number of patients, %: Percentage of patients

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14.1.2 Subject disposition - excluded - country wise – ALL analysis set

	Excluded based on inclusion criteria					Excluded based on exclusion criteria	Excluded based on any exclusion or inclusion criteria
	1	2	3	4	5	6	
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Total (N=2446)	1 (0.04)	1 (0.04)	8 (0.33)	3 (0.12)	55 (2.25)	12 (0.49)	73 (2.98)
Croatia (N=311)							
Denmark (N=627)			3 (0.48)		13 (2.07)	4 (0.64)	20 (3.19)
Finland (N=150)		1 (0.67)			1 (0.67)		2 (1.33)
France (N=165)					3 (1.82)	1 (0.61)	4 (2.42)
Germany (N=35)					1 (2.86)		1 (2.86)
Greece (N=11)							
Ireland (N=74)					1 (1.35)		1 (1.35)
Israel (N=215)					3 (1.40)		3 (1.40)
Italy (N=70)			1 (1.43)		2 (2.86)	2 (2.86)	5 (7.14)
Malaysia (N=27)					3 (11.11)		3 (11.11)
Netherlands (N=70)			1 (1.43)		7 (10.00)	2 (2.86)	9 (12.86)
Norway (N=45)							
Poland (N=127)							
Portugal (N=19)						1 (5.26)	1 (5.26)
Romania (N=26)							
Spain (N=168)	1 (0.60)		1 (0.60)	2 (1.19)	11 (6.55)	1 (0.60)	11 (6.55)
United Kingdom (N=306)			2 (0.65)	1 (0.33)	10 (3.27)	1 (0.33)	13 (4.25)

N: Number of patients, SD: Standard deviation
1: Informed consent obtained before any data collection.
2: Woman with positive pregnancy test.
3: Diabetes mellitus type 1 or type 2 diagnosed prior to conception.
4: Currently treated with Levemir or other injectable anti-diabetic treatment.
5: Unchanged anti-diabetic treatment 4 weeks prior to and following conception.
6: Woman who have been pregnant for more than 16 weeks at baseline visit.
Percentages are based on total number of patients in the analysis set with information.

14.1.3 Subject disposition - discontinued and completed - country wise – FAS_MOTHER analysis set

	Discontinued on criteria*					Total Discontinued on criteria*	Completed on criteria**			Total Completed on criteria**
	1 N (%)	2 N (%)	3 N (%)	4 N (%)	5 N (%)	N (%)	1 N (%)	2 N (%)	3 N (%)	N (%)
Total(2373)	1(0.0)	18(0.8)	133(5.6)	12(0.5)		164(6.9)	1995(84.1)	213(9.0)	1(0.0)	2209(93.1)
Country										
Croatia(311)		3(1.0)	1(0.3)			4(1.3)	277(89.1)	30(9.6)		307(98.7)
Denmark(607)		1(0.2)	31(5.1)			32(5.3)	538(88.6)	37(6.1)		575(94.7)
Finland(148)			1(0.7)			1(0.7)	136(91.9)	11(7.4)		147(99.3)
France(161)		4(2.5)	17(10.6)	1(0.6)		22(13.7)	125(77.6)	13(8.1)	1(0.6)	139(86.3)
Germany(34)		1(2.9)	1(2.9)			2(5.9)	29(85.3)	3(8.8)		32(94.1)
Greece(11)							10(90.9)	1(9.1)		11(100)
Ireland(73)			9(12.3)			9(12.3)	53(72.6)	11(15.1)		64(87.7)
Israel(212)	1(0.5)	3(1.4)	7(3.3)			11(5.2)	175(82.5)	26(12.3)		201(94.8)
Italy(65)		2(3.1)				2(3.1)	60(92.3)	3(4.6)		63(96.9)
Malaysia(24)			1(4.2)			1(4.2)	21(87.5)	2(8.3)		23(95.8)
Netherlands(61)			1(1.6)			1(1.6)	54(88.5)	6(9.8)		60(98.4)
Norway(45)			1(2.2)	9(20.0)		10(22.2)	30(66.7)	5(11.1)		35(77.8)
Poland(127)		1(0.8)	1(0.8)			2(1.6)	111(87.4)	14(11.0)		125(98.4)
Portugal(18)			2(11.1)			2(11.1)	12(66.7)	4(22.2)		16(88.9)
Romania(26)							26(100)			26(100)
Spain(157)		1(0.6)	4(2.5)	1(0.6)		6(3.8)	139(88.5)	12(7.6)		151(96.2)
United Kingdom(293)		2(0.7)	56(19.1)	1(0.3)		59(20.1)	199(67.9)	35(11.9)		234(79.9)

N: Number of patients, %: Percentage of patients
*Criteria: 1: Adverse event, 2: withdrawal by the participant, 3: lost to follow-up, 4: other reason for discontinuation, 5: Missing.
**Criteria: 1: completion of the 1-year infant examination, 2: death of foetus/infant, 3: Missing.

14.1.4 Subject disposition - discontinued and completed - country wise – MOTHER analysis set

	Discontinued on criteria*					Total Discontinued on criteria*	Completed on criteria**			Total Completed on criteria**
	1 N (%)	2 N (%)	3 N (%)	4 N (%)	5 N (%)	N (%)	1 N (%)	2 N (%)	3 N (%)	N (%)
Total(1457)		4(0.3)	75(5.1)	4(0.3)		83(5.7)	1241(85.2)	133(9.1)		1374(94.3)
Country										
Croatia(285)		1(0.4)	1(0.4)			2(0.7)	255(89.5)	28(9.8)		283(99.3)
Denmark(383)		1(0.3)	15(3.9)			16(4.2)	345(90.1)	22(5.7)		367(95.8)
Finland(107)							98(91.6)	9(8.4)		107(100)
France(24)		1(4.2)	1(4.2)			2(8.3)	19(79.2)	3(12.5)		22(91.7)
Germany(13)			1(7.7)			1(7.7)	10(76.9)	2(15.4)		12(92.3)
Greece(11)							10(90.9)	1(9.1)		11(100)
Ireland(59)			7(11.9)			7(11.9)	43(72.9)	9(15.3)		52(88.1)
Israel(61)		1(1.6)	3(4.9)			4(6.6)	51(83.6)	6(9.8)		57(93.4)
Italy(36)							34(94.4)	2(5.6)		36(100)
Malaysia(19)							17(89.5)	2(10.5)		19(100)
Netherlands(17)			1(5.9)			1(5.9)	16(94.1)			16(94.1)
Norway(24)				3(12.5)		3(12.5)	16(66.7)	5(20.8)		21(87.5)
Poland(57)			1(1.8)			1(1.8)	50(87.7)	6(10.5)		56(98.2)
Portugal(15)			1(6.7)			1(6.7)	11(73.3)	3(20.0)		14(93.3)
Romania(23)							23(100)			23(100)
Spain(114)			4(3.5)			4(3.5)	101(88.6)	9(7.9)		110(96.5)
United Kingdom(209)			40(19.1)	1(0.5)		41(19.6)	142(67.9)	26(12.4)		168(80.4)

N: Number of patients, %: Percentage of patients
*Criteria: 1: Adverse event, 2: withdrawal by the participant, 3: lost to follow-up, 4: other reason for discontinuation, 5: Missing.
**Criteria: 1: completion of the 1-year infant examination, 2: death of foetus/infant, 3: Missing.

14.1.5 Subject disposition - discontinued and completed - by basal insulin treatment group at enrolment – FAS_MOTHER analysis set

	Discontinued on criteria*					Total Discontinued on criteria*	Completed on criteria**			Total Completed on criteria**
	1 N (%)	2 N (%)	3 N (%)	4 N (%)	5 N (%)	N (%)	1 N (%)	2 N (%)	3 N (%)	N (%)
Levemir/Insulin Detemir(764)		7(0.9)	41(5.4)	3(0.4)		51(6.7)	646(84.6)	67(8.8)		713(93.3)
Other Basal Insulin(828)		7(0.8)	53(6.4)	1(0.1)		61(7.4)	693(83.7)	74(8.9)		767(92.6)
No Basal Insulin(781)	1(0.1)	4(0.5)	39(5.0)	8(1.0)		52(6.7)	656(84.0)	72(9.2)	1(0.1)	729(93.3)

N: Number of patients, %: Percentage of patients
*Criteria: 1: Adverse event, 2: withdrawal by the participant, 3: lost to follow-up, 4: other reason for discontinuation, 5: Missing.
**Criteria: 1: completion of the 1-year infant examination, 2: death of foetus/infant, 3: Missing.

14.1.6 Subject disposition - discontinued and completed – by basal insulin treatment group at enrolment– MOTHER analysis set

	Discontinued on criteria*					Total Discontinued on criteria*	Completed on criteria**			Total Completed on criteria**
	1 N (%)	2 N (%)	3 N (%)	4 N (%)	5 N (%)	N (%)	1 N (%)	2 N (%)	3 N (%)	N (%)
Levemir/Insulin Detemir(727)		2(0.3)	38(5.2)	3(0.4)		43(5.9)	622(85.6)	62(8.5)		684(94.1)
Other Basal Insulin(730)		2(0.3)	37(5.1)	1(0.1)		40(5.5)	619(84.8)	71(9.7)		690(94.5)

N: Number of patients, %: Percentage of patients
*Criteria: 1: Adverse event, 2: withdrawal by the participant, 3: lost to follow-up, 4: other reason for discontinuation, 5: Missing.
**Criteria: 1: completion of the 1-year infant examination, 2: death of foetus/infant, 3: Missing.

14.1.7 Subject disposition – participation more than once – FAS_MOTHER analysis set

	Participation in the study		
	Once N (%)	Twice N (%)	Thrice N (%)
Number of subjects (N=2373)	2007 (84.6)	336 (14.2)	30 (1.3)
Country			
Croatia (N=311)	252 (81.0)	50 (16.1)	9 (2.9)
Denmark (N=607)	498 (82.0)	106 (17.5)	3 (0.5)
Finland (N=148)	134 (90.5)	14 (9.5)	
France (N=161)	147 (91.3)	14 (8.7)	
Germany (N=34)	34 (100)		
Greece (N=11)	11 (100)		
Ireland (N=73)	65 (89.0)	8 (11.0)	
Israel (N=212)	137 (64.6)	60 (28.3)	15 (7.1)
Italy (N=65)	63 (96.9)	2 (3.1)	
Malaysia (N=24)	24 (100)		
Netherlands (N=61)	55 (90.2)	6 (9.8)	
Norway (N=45)	39 (86.7)	6 (13.3)	
Poland (N=127)	107 (84.3)	20 (15.7)	
Portugal (N=18)	18 (100)		
Romania (N=26)	26 (100)		
Spain (N=157)	145 (92.4)	12 (7.6)	
United Kingdom (N=293)	252 (86.0)	38 (13.0)	3 (1.0)

N: Number of patients, %: Percentage of patients

14.1.8 Subject disposition – participation more than once – MOTHER analysis set

	Participation in the study		
	Once N (%)	Twice N (%)	Thrice N (%)
Number of subjects (N=1457)	1244 (85.4)	193 (13.2)	20 (1.4)
Country			
Croatia (N=285)	232 (81.4)	45 (15.8)	8 (2.8)
Denmark (N=383)	316 (82.5)	64 (16.7)	3 (0.8)
Finland (N=107)	97 (90.7)	10 (9.3)	
France (N=24)	24 (100)		
Germany (N=13)	13 (100)		
Greece (N=11)	11 (100)		
Ireland (N=59)	53 (89.8)	6 (10.2)	
Israel (N=61)	38 (62.3)	17 (27.9)	6 (9.8)
Italy (N=36)	34 (94.4)	2 (5.6)	
Malaysia (N=19)	19 (100)		
Netherlands (N=17)	15 (88.2)	2 (11.8)	
Norway (N=24)	18 (75.0)	6 (25.0)	
Poland (N=57)	48 (84.2)	9 (15.8)	
Portugal (N=15)	15 (100)		
Romania (N=23)	23 (100)		
Spain (N=114)	108 (94.7)	6 (5.3)	
United Kingdom (N=209)	180 (86.1)	26 (12.4)	3 (1.4)

N: Number of patients, %: Percentage of patients

nis-primary/nn304-4016/20200312_nsr_er
10AUG2020:08:37:39 - t_subj_disp/t_disp_part_mother.txt

14.1.9 Subject disposition – participation more than once – by treatment at enrolment - FAS_MOTHER analysis set

	Participation in the study		
	Once N (%)	Twice N (%)	Thrice N (%)
Number of subjects (N=2373)	2007 (84.6)	336 (14.2)	30 (1.3)
Levemir/Insulin Detemir (N=764)	638 (83.5)	112 (14.7)	14 (1.8)
Other Basal Insulin (N=828)	733 (88.5)	88 (10.6)	7 (0.8)
No Basal Insulin (N=781)	636 (81.4)	136 (17.4)	9 (1.2)

N: Number of patients, %: Percentage of patients

nis-primary/nn304-4016/20200312_nsr_er
10AUG2020:08:37:39 - t_subj_disp_trt/t_disp_part_trt_fas_mother.txt

14.1.10 Subject disposition – participation more than once – by treatment at enrolment - MOTHER analysis set

	Participation in the study		
	Once N (%)	Twice N (%)	Thrice N (%)
Number of subjects (N=1457)	1244 (85.4)	193 (13.2)	20 (1.4)
Levemir/Insulin Detemir (N=727)	606 (83.4)	108 (14.9)	13 (1.8)
Other Basal Insulin (N=730)	638 (87.4)	85 (11.6)	7 (1.0)

N: Number of patients, %: Percentage of patients

nis-primary/nn304-4016/20200312_nsr_er
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14.1.11 Subject disposition – visits – FAS_MOTHER analysis set

	Visits									
	Enrolment		Standard routine		Delivery		1 month follow-up		1 year follow-up	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects(N= 2373)	2373	(100.0)	2223	(93.7)	2347	(98.9)	2036	(85.8)	2000	(84.3)
Country										
Croatia(N= 311)	311	(100.0)	284	(91.3)	309	(99.4)	278	(89.4)	277	(89.1)
Denmark(N= 607)	607	(100.0)	584	(96.2)	601	(99.0)	546	(90.0)	538	(88.6)
Finland(N= 148)	148	(100.0)	141	(95.3)	147	(99.3)	135	(91.2)	136	(91.9)
France(N= 161)	161	(100.0)	151	(93.8)	157	(97.5)	114	(70.8)	125	(77.6)
Germany(N= 34)	34	(100.0)	33	(97.1)	34	(100.0)	31	(91.2)	29	(85.3)
Greece(N= 11)	11	(100.0)	10	(90.9)	11	(100.0)	10	(90.9)	10	(90.9)
Ireland(N= 73)	73	(100.0)	67	(91.8)	73	(100.0)	58	(79.5)	53	(72.6)
Israel(N= 212)	212	(100.0)	194	(91.5)	208	(98.1)	181	(85.4)	175	(82.5)
Italy(N= 65)	65	(100.0)	63	(96.9)	63	(96.9)	60	(92.3)	60	(92.3)
Malaysia(N= 24)	24	(100.0)	23	(95.8)	23	(95.8)	21	(87.5)	21	(87.5)
Netherlands(N= 61)	61	(100.0)	57	(93.4)	61	(100.0)	54	(88.5)	54	(88.5)
Norway(N= 45)	45	(100.0)	41	(91.1)	44	(97.8)	30	(66.7)	30	(66.7)
Poland(N= 127)	127	(100.0)	114	(89.8)	126	(99.2)	112	(88.2)	111	(87.4)
Portugal(N= 18)	18	(100.0)	16	(88.9)	17	(94.4)	13	(72.2)	12	(66.7)
Romania(N= 26)	26	(100.0)	26	(100.0)	26	(100.0)	26	(100.0)	26	(100.0)
Spain(N= 157)	157	(100.0)	148	(94.3)	157	(100.0)	144	(91.7)	139	(88.5)
United Kingdom(N= 293)	293	(100.0)	271	(92.5)	290	(99.0)	223	(76.1)	204	(69.6)

N: Number of patients, %: Percentage of patients

14.1.12 Subject disposition – visits – MOTHER analysis set

	Visits									
	Enrolment		Standard routine		Delivery		1 month follow-up		1 year follow-up	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects(N= 1457)	1457	(100.0)	1363	(93.5)	1456	(99.9)	1273	(87.4)	1246	(85.5)
Country										
Croatia(N= 285)	285	(100.0)	261	(91.6)	285	(100.0)	256	(89.8)	255	(89.5)
Denmark(N= 383)	383	(100.0)	372	(97.1)	383	(100.0)	350	(91.4)	345	(90.1)
Finland(N= 107)	107	(100.0)	101	(94.4)	107	(100.0)	97	(90.7)	98	(91.6)
France(N= 24)	24	(100.0)	21	(87.5)	23	(95.8)	14	(58.3)	19	(79.2)
Germany(N= 13)	13	(100.0)	13	(100.0)	13	(100.0)	11	(84.6)	10	(76.9)
Greece(N= 11)	11	(100.0)	10	(90.9)	11	(100.0)	10	(90.9)	10	(90.9)
Ireland(N= 59)	59	(100.0)	54	(91.5)	59	(100.0)	46	(78.0)	43	(72.9)
Israel(N= 61)	61	(100.0)	55	(90.2)	61	(100.0)	54	(88.5)	51	(83.6)
Italy(N= 36)	36	(100.0)	36	(100.0)	36	(100.0)	34	(94.4)	34	(94.4)
Malaysia(N= 19)	19	(100.0)	18	(94.7)	19	(100.0)	17	(89.5)	17	(89.5)
Netherlands(N= 17)	17	(100.0)	17	(100.0)	17	(100.0)	17	(100.0)	16	(94.1)
Norway(N= 24)	24	(100.0)	20	(83.3)	24	(100.0)	16	(66.7)	16	(66.7)
Poland(N= 57)	57	(100.0)	50	(87.7)	57	(100.0)	51	(89.5)	50	(87.7)
Portugal(N= 15)	15	(100.0)	14	(93.3)	15	(100.0)	12	(80.0)	11	(73.3)
Romania(N= 23)	23	(100.0)	23	(100.0)	23	(100.0)	23	(100.0)	23	(100.0)
Spain(N= 114)	114	(100.0)	106	(93.0)	114	(100.0)	105	(92.1)	101	(88.6)
United Kingdom(N= 209)	209	(100.0)	192	(91.9)	209	(100.0)	160	(76.6)	147	(70.3)

N: Number of patients, %: Percentage of patients

14.1.13 Subject disposition – visits – basal insulin treatment group at enrolment - FAS_MOTHER analysis set

	Visits									
	Enrolment		Standard routine		Delivery		1 month follow-up		1 year follow-up	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects(N= 2373)	2373	(100.0)	2223	(93.7)	2347	(98.9)	2036	(85.8)	2000	(84.3)
Treatment										
Levemir/Insulin Detemir(N= 764)	764	(100.0)	708	(92.7)	757	(99.1)	666	(87.2)	650	(85.1)
No Basal Insulin(N= 781)	781	(100.0)	735	(94.1)	775	(99.2)	662	(84.8)	656	(84.0)
Other Basal Insulin(N= 828)	828	(100.0)	780	(94.2)	815	(98.4)	708	(85.5)	694	(83.8)

N: Number of patients, %: Percentage of patients

nis-primary/nn304-4016/20200312_nsr_er
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14.1.14 Subject disposition – visits – basal insulin treatment group at enrolment - MOTHER analysis set

	Visits									
	Enrolment		Standard routine		Delivery		1 month follow-up		1 year follow-up	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects(N= 1457)	1457	(100.0)	1363	(93.5)	1456	(99.9)	1273	(87.4)	1246	(85.5)
Treatment										
Levemir/Insulin Detemir(N= 727)	727	(100.0)	677	(93.1)	727	(100.0)	642	(88.3)	626	(86.1)
Other Basal Insulin(N= 730)	730	(100.0)	686	(94.0)	729	(99.9)	631	(86.4)	620	(84.9)

N: Number of patients, %: Percentage of patients

nis-primary/nn304-4016/20200312_nsr_er
10AUG2020:08:37:18 - t_disp_vis/t_disp_vis_bas_trt_mother.txt

14.1.15 Subject disposition – basal insulin treatment group at enrolment - number of records – ALL analysis set

	Levemir/Insulin Detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)
ALL(2446)	791 (32.3)	858 (35.1)	797 (32.6)
FAS_MOTHER(2373)	764 (32.2)	828 (34.9)	781 (32.9)
FAS_FOETUS(2396)	773 (32.3)	828 (34.6)	795 (33.2)
FAS_LIVEBORN(2186)	709 (32.4)	754 (34.5)	723 (33.1)
FAS_INFANT(2043)	664 (32.5)	705 (34.5)	674 (33.0)
MOTHER(1457)	727 (49.9)	730 (50.1)	
FOETUS(1481)	741 (50.0)	740 (50.0)	
LIVEBORN(1351)	682 (50.5)	669 (49.5)	
INFANT(1268)	638 (50.3)	630 (49.7)	
PRIMARY(1360)	684 (50.3)	676 (49.7)	

N: Number of patients, %: Percentage of patients

14.1.16 Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
Number of subjects	764		828		781		2373	
Demographic and socioeconomic information								
Country, N(%)								
N	764		828		781		2373	
Croatia	240	(31.4)	47	(5.7)	24	(3.1)	311	(13.1)
Denmark	127	(16.6)	282	(34.1)	198	(25.4)	607	(25.6)
Finland	59	(7.7)	53	(6.4)	36	(4.6)	148	(6.2)
France	15	(2.0)	39	(4.7)	107	(13.7)	161	(6.8)
Germany	4	(0.5)	11	(1.3)	19	(2.4)	34	(1.4)
Greece	4	(0.5)	7	(0.8)			11	(0.5)
Ireland	28	(3.7)	34	(4.1)	11	(1.4)	73	(3.1)
Israel	65	(8.5)	17	(2.1)	130	(16.6)	212	(8.9)
Italy	16	(2.1)	27	(3.3)	22	(2.8)	65	(2.7)
Malaysia	6	(0.8)	17	(2.1)	1	(0.1)	24	(1.0)
Netherlands	13	(1.7)	6	(0.7)	42	(5.4)	61	(2.6)
Norway	5	(0.7)	22	(2.7)	18	(2.3)	45	(1.9)
Poland	20	(2.6)	41	(5.0)	66	(8.5)	127	(5.4)
Portugal	4	(0.5)	13	(1.6)	1	(0.1)	18	(0.8)
Romania	22	(2.9)	1	(0.1)	3	(0.4)	26	(1.1)
Spain	27	(3.5)	92	(11.1)	38	(4.9)	157	(6.6)
United Kingdom	109	(14.3)	119	(14.4)	65	(8.3)	293	(12.3)
Age								
N	764		828		781		2373	
Mean (SD)	31.04	(5.12)	30.56	(5.30)	30.96	(4.90)	30.85	(5.12)
Median	31.00		30.00		31.00		31.00	
2.5; 97.5 percentiles	21.00; 40.00		21.00; 41.00		22.00; 41.00		21.00; 41.00	
Min, Max	18.00; 44.00		17.00; 47.00		18.00; 44.00		17.00; 47.00	

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
Race, N(%)								
N	749		789		669		2207	
Asian	13	(1.7)	33	(4.2)	2	(0.3)	48	(2.2)
Black or African American	8	(1.1)	10	(1.3)	1	(0.1)	19	(0.9)
Native Hawaiian or other Pacific Islander			1	(0.1)			1	(<0.1)
White	715	(95.5)	713	(90.4)	653	(97.6)	2081	(94.3)
Other	13	(1.7)	32	(4.1)	13	(1.9)	58	(2.6)
Education, N(%)								
N	701		741		675		2117	
University degree	210	(30.0)	169	(22.8)	285	(42.2)	664	(31.4)
College degree	90	(12.8)	122	(16.5)	131	(19.4)	343	(16.2)
Graduate school	133	(19.0)	97	(13.1)	80	(11.9)	310	(14.6)
Technical school	49	(7.0)	52	(7.0)	46	(6.8)	147	(6.9)
High school	103	(14.7)	115	(15.5)	57	(8.4)	275	(13.0)
A levels	25	(3.6)	22	(3.0)	12	(1.8)	59	(2.8)
Intermediate school leaving certificate	20	(2.9)	46	(6.2)	26	(3.9)	92	(4.3)
Basic school leaving certificate	22	(3.1)	36	(4.9)	10	(1.5)	68	(3.2)
Primary school	8	(1.1)	16	(2.2)	6	(0.9)	30	(1.4)
No education	4	(0.6)	14	(1.9)	2	(0.3)	20	(0.9)
Other	37	(5.3)	52	(7.0)	20	(3.0)	109	(5.1)
Occupation, N(%)								
N	724		782		734		2240	
Managerial (employed or self-employed)	100	(13.8)	43	(5.5)	55	(7.5)	198	(8.8)
Professional and higher technical	132	(18.2)	134	(17.1)	185	(25.2)	451	(20.1)
Clerical or lower technical	76	(10.5)	68	(8.7)	63	(8.6)	207	(9.2)
Skilled worker	182	(25.1)	180	(23.0)	227	(30.9)	589	(26.3)
Semiskilled worker	40	(5.5)	58	(7.4)	28	(3.8)	126	(5.6)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
Unskilled worker	16	(2.2)	49	(6.3)	28	(3.8)	93	(4.2)
Student	27	(3.7)	47	(6.0)	41	(5.6)	115	(5.1)
Not working	116	(16.0)	153	(19.6)	74	(10.1)	343	(15.3)
Other	35	(4.8)	50	(6.4)	33	(4.5)	118	(5.3)
Tobacco , N(%)								
N	746		799		766		2311	
Never	583	(78.2)	579	(72.5)	592	(77.3)	1754	(75.9)
Previous	92	(12.3)	142	(17.8)	132	(17.2)	366	(15.8)
Current	71	(9.5)	78	(9.8)	42	(5.5)	191	(8.3)
Alcohol , N(%)								
N	734		782		748		2264	
Yes	7	(1.0)	12	(1.5)	6	(0.8)	25	(1.1)
No	727	(99.0)	770	(98.5)	742	(99.2)	2239	(98.9)
Obstetric history								
Number of previous pregnancies, N(%)								
N	763		828		781		2372	
0	243	(31.8)	289	(34.9)	302	(38.7)	834	(35.2)
1	275	(36.0)	276	(33.3)	223	(28.6)	774	(32.6)
2	121	(15.9)	135	(16.3)	146	(18.7)	402	(16.9)
3	64	(8.4)	68	(8.2)	56	(7.2)	188	(7.9)
4+	60	(7.9)	60	(7.2)	54	(6.9)	174	(7.3)
Number of previous live births, N(%)								
N	742		756		734		2232	
0	344	(46.4)	329	(43.5)	335	(45.6)	1008	(45.2)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
1	292	(39.4)	311	(41.1)	283	(38.6)	886	(39.7)
2	80	(10.8)	91	(12.0)	87	(11.9)	258	(11.6)
3	14	(1.9)	20	(2.6)	18	(2.5)	52	(2.3)
4+	12	(1.6)	5	(0.7)	11	(1.5)	28	(1.3)
Previous Pregnancy Complications (Y/N), N(%)								
N	729		738		687		2154	
Yes	390	(53.5)	404	(54.7)	360	(52.4)	1154	(53.6)
No	339	(46.5)	334	(45.3)	327	(47.6)	1000	(46.4)
Previous pre-eclampsia, N(%)								
N	764		828		781		2373	
Yes	29	(3.8)	37	(4.5)	45	(5.8)	111	(4.7)
No	735	(96.2)	791	(95.5)	736	(94.2)	2262	(95.3)
Previous caesarean section, N(%)								
N	764		828		781		2373	
Yes	179	(23.4)	146	(17.6)	171	(21.9)	496	(20.9)
No	585	(76.6)	682	(82.4)	610	(78.1)	1877	(79.1)
Previous perinatal deaths, N(%)								
N	764		828		781		2373	
Yes	14	(1.8)	13	(1.6)	10	(1.3)	37	(1.6)
No	750	(98.2)	815	(98.4)	771	(98.7)	2336	(98.4)
Previous preterm delivery , N(%)								
N	764		828		781		2373	
Yes	47	(6.2)	63	(7.6)	50	(6.4)	160	(6.7)
No	717	(93.8)	765	(92.4)	731	(93.6)	2213	(93.3)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
Previous spontaneous abortion, N(%)								
N	764		828		781		2373	
Yes	194	(25.4)	180	(21.7)	165	(21.1)	539	(22.7)
No	570	(74.6)	648	(78.3)	616	(78.9)	1834	(77.3)
Previous malformations, N(%)								
N	764		828		781		2373	
Yes	17	(2.2)	18	(2.2)	15	(1.9)	50	(2.1)
No	747	(97.8)	810	(97.8)	766	(98.1)	2323	(97.9)
Previous minor malformations, N(%)								
N	764		828		781		2373	
Yes	2	(0.3)	7	(0.8)	3	(0.4)	12	(0.5)
No	762	(99.7)	821	(99.2)	778	(99.6)	2361	(99.5)
Previous major malformations, N(%)								
N	764		828		781		2373	
Yes	15	(2.0)	11	(1.3)	12	(1.5)	38	(1.6)
No	749	(98.0)	817	(98.7)	769	(98.5)	2335	(98.4)
Other pregnancy complications								
N	764		828		781		2373	
Yes	88	(11.5)	128	(15.5)	98	(12.5)	314	(13.2)
No	676	(88.5)	700	(84.5)	683	(87.5)	2059	(86.8)
Medical history								
Hypertension, N(%)								
N	764		827		781		2372	

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
Yes	64	(8.4)	69	(8.3)	53	(6.8)	186	(7.8)
No	700	(91.6)	758	(91.7)	728	(93.2)	2186	(92.2)
Epilepsy, N(%)								
N	761		827		781		2369	
Yes	13	(1.7)	15	(1.8)	10	(1.3)	38	(1.6)
No	748	(98.3)	812	(98.2)	771	(98.7)	2331	(98.4)
Thyroid disorder, N(%)								
N	763		825		780		2368	
Yes	183	(24.0)	198	(24.0)	258	(33.1)	639	(27.0)
No	580	(76.0)	627	(76.0)	522	(66.9)	1729	(73.0)
Asthma, N(%)								
N	762		827		779		2368	
Yes	34	(4.5)	51	(6.2)	40	(5.1)	125	(5.3)
No	728	(95.5)	776	(93.8)	739	(94.9)	2243	(94.7)
Heart disease, N(%)								
N	763		825		780		2368	
Yes	5	(0.7)	11	(1.3)	7	(0.9)	23	(1.0)
No	758	(99.3)	814	(98.7)	773	(99.1)	2345	(99.0)
Psychiatric disorder, N(%)								
N	764		825		780		2369	
Yes	54	(7.1)	71	(8.6)	71	(9.1)	196	(8.3)
No	710	(92.9)	754	(91.4)	709	(90.9)	2173	(91.7)
Inheritable diseases, N(%)								

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER

	Insulin detemir	Other basal insulin	No basal insulin	Total
N	759	822	778	2359
Yes	28 (3.7)	31 (3.8)	16 (2.1)	75 (3.2)
No	731 (96.3)	791 (96.2)	762 (97.9)	2284 (96.8)
Diabetes history				
Type of DM, N(%)				
N	764	828	781	2373
T1DM	625 (81.8)	730 (88.2)	760 (97.3)	2115 (89.1)
T2DM	139 (18.2)	98 (11.8)	21 (2.7)	258 (10.9)
Diabetes duration				
N	760	821	781	2362
Mean (SD)	13.13 (8.16)	13.54 (8.47)	17.99 (7.92)	14.88 (8.48)
Median	12.00	13.00	18.00	15.00
2.5; 97.5 percentiles	2.00; 30.00	2.00; 30.00	4.00; 33.00	2.00; 31.00
Min, Max	1.00; 37.00	1.00; 38.00	1.00; 40.00	1.00; 40.00
Diabetes duration, N(%)				
N	760	821	781	2362
<5 years	129 (17.0)	148 (18.0)	32 (4.1)	309 (13.1)
>= 5 years	631 (83.0)	673 (82.0)	749 (95.9)	2053 (86.9)
History of diabetes complications, N(%)				
N	762	826	781	2369
Yes	194 (25.5)	198 (24.0)	294 (37.6)	686 (29.0)
No	568 (74.5)	628 (76.0)	487 (62.4)	1683 (71.0)
History of microvascular complications, N(%)				

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
N	762		824		781		2367	
Yes	194	(25.5)	198	(24.0)	293	(37.5)	685	(28.9)
No	568	(74.5)	626	(76.0)	488	(62.5)	1682	(71.1)
History of macrovascular complications, N(%)								
N	761		825		781		2367	
Yes	2	(0.3)	3	(0.4)	3	(0.4)	8	(0.3)
No	759	(99.7)	822	(99.6)	778	(99.6)	2359	(99.7)
History of retinopathy, N(%)								
N	761		821		779		2361	
Yes	162	(21.3)	184	(22.4)	271	(34.8)	617	(26.1)
No	599	(78.7)	637	(77.6)	508	(65.2)	1744	(73.9)
History of neuropathy, N(%)								
N	761		821		780		2362	
Yes	32	(4.2)	10	(1.2)	27	(3.5)	69	(2.9)
No	729	(95.8)	811	(98.8)	753	(96.5)	2293	(97.1)
History of nephropathy, N(%)								
N	760		823		780		2363	
Yes	36	(4.7)	33	(4.0)	35	(4.5)	104	(4.4)
No	724	(95.3)	790	(96.0)	745	(95.5)	2259	(95.6)
History of macroangiopathy (including peripheral vascular disease), N(%)								
N	761		823		779		2363	
Yes	2	(0.3)	2	(0.2)	3	(0.4)	7	(0.3)
No	759	(99.7)	821	(99.8)	776	(99.6)	2356	(99.7)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER

	Insulin detemir	Other basal insulin	No basal insulin	Total
History of unstable angina, N(%)				
N	756	823	775	2354
Yes		1 (0.1)		1 (<0.1)
No	756 (100.0)	822 (99.9)	775 (100.0)	2353 (100)
History of heart failure, N(%)				
N	743	822	774	2339
No	743 (100.0)	822 (100.0)	774 (100.0)	2339 (100.0)
Current pregnancy				
Gestational age at enrolment (weeks)				
N	760	821	781	2362
Mean (SD)	8.72 (2.48)	8.82 (2.59)	8.41 (2.50)	8.65 (2.53)
Median	8.00	8.00	8.00	8.00
2.5; 97.5 percentiles	5.00; 14.00	4.00; 15.00	4.00; 14.00	4.00; 14.00
Min, Max	2.00; 16.00	2.00; 16.00	2.00; 16.00	2.00; 16.00
Gestational age at enrolment (weeks), N(%)				
N	760	821	781	2362
<7	156 (20.5)	164 (20.0)	184 (23.6)	504 (21.3)
>=7 - 12	494 (65.0)	528 (64.3)	506 (64.8)	1528 (64.7)
>=12 - 16	110 (14.5)	129 (15.7)	91 (11.7)	330 (14.0)
Folic acid taken before and during first trimester, N(%)				
N	754	820	762	2336
Yes	484 (64.2)	644 (78.5)	651 (85.4)	1779 (76.2)
No	270 (35.8)	176 (21.5)	111 (14.6)	557 (23.8)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER

	Insulin detemir	Other basal insulin	No basal insulin	Total
HbA1c, anthropometric measurements and vital signs at enrolment				
HbA1c				
N	724	777	737	2238
Mean (SD)	7.00 (1.30)	7.19 (1.42)	6.81 (0.94)	7.01 (1.25)
Median	6.73	6.82	6.70	6.73
2.5; 97.5 percentiles	5.20; 10.50	5.35; 10.60	5.35; 9.10	5.30; 10.20
Min, Max	4.40; 13.90	4.71; 14.50	4.70; 13.90	4.40; 14.50
HbA1c (<7%), N(%)				
N	724	777	737	2238
Yes	433 (59.8)	435 (56.0)	495 (67.2)	1363 (60.9)
No	291 (40.2)	342 (44.0)	242 (32.8)	875 (39.1)
HbA1c (<6.5%), N(%)				
N	724	777	737	2238
Yes	282 (39.0)	279 (35.9)	273 (37.0)	834 (37.3)
No	442 (61.0)	498 (64.1)	464 (63.0)	1404 (62.7)
HbA1c%), N(%)				
N	724	777	737	2238
<5.5	45 (6.2)	34 (4.4)	27 (3.7)	106 (4.7)
>= 5.5 to 6.0	102 (14.1)	100 (12.9)	81 (11.0)	283 (12.6)
>=6.0 to 6.5	135 (18.6)	145 (18.7)	165 (22.4)	445 (19.9)
>=6.5 to 7.0	151 (20.9)	156 (20.1)	222 (30.1)	529 (23.6)
>=7.0 to 7.5	88 (12.2)	77 (9.9)	105 (14.2)	270 (12.1)
>=7.5 to 8.0	70 (9.7)	71 (9.1)	66 (9.0)	207 (9.2)
>=8.0 to 8.5	46 (6.4)	70 (9.0)	31 (4.2)	147 (6.6)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER

	Insulin detemir	Other basal insulin	No basal insulin	Total
>=8.5 to 9.0	29 (4.0)	39 (5.0)	18 (2.4)	86 (3.8)
>=9.0 to 9.5	19 (2.6)	36 (4.6)	10 (1.4)	65 (2.9)
>=9.5	39 (5.4)	49 (6.3)	12 (1.6)	100 (4.5)
Weight (kg)				
N	736	794	729	2259
Mean (SD)	71.10 (16.12)	73.82 (16.77)	73.62 (14.62)	72.87 (15.93)
Median	67.30	70.00	71.10	70.00
2.5; 97.5 percentiles	50.30; 115.00	51.00; 117.00	53.20; 107.30	51.00; 115.00
Min, Max	43.00; 150.00	44.00; 141.60	45.20; 183.00	43.00; 183.00
BMI (kg/m2)				
N	734	788	724	2246
Mean (SD)	25.81 (5.75)	26.82 (5.71)	26.46 (4.94)	26.38 (5.50)
Median	24.30	25.45	25.60	25.10
2.5; 97.5 percentiles	18.60; 40.80	19.10; 41.90	19.90; 37.80	19.00; 40.60
Min, Max	16.30; 52.50	16.40; 49.00	17.50; 66.40	16.30; 66.40
BMI (kg/m2)%), N(%)				
N	734	788	724	2246
<18.5	14 (1.9)	8 (1.0)	2 (0.3)	24 (1.1)
>= 18.5 to 25.0	401 (54.6)	360 (45.7)	307 (42.4)	1068 (47.6)
>=25.0 to 30.0	182 (24.8)	234 (29.7)	279 (38.5)	695 (30.9)
>=30.0 to 35.0	76 (10.4)	108 (13.7)	98 (13.5)	282 (12.6)
>=35.0 to 40.0	39 (5.3)	48 (6.1)	25 (3.5)	112 (5.0)
>=40.0	22 (3.0)	30 (3.8)	13 (1.8)	65 (2.9)
Systolic blood pressure (mmHg)				
N	704	748	667	2119

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER

	Insulin detemir	Other basal insulin	No basal insulin	Total
Mean (SD)	117.53 (13.67)	119.23 (13.76)	118.57 (13.19)	118.46 (13.57)
Median	119.00	120.00	119.00	119.00
2.5; 97.5 percentiles	90.00; 146.00	95.00; 149.00	95.00; 145.00	92.00; 146.00
Min, Max	80.00; 183.00	83.00; 188.00	80.00; 198.00	80.00; 198.00
Systolic blood pressure (mmHg)%), N(%)				
N	704	748	667	2119
<130	563 (80.0)	576 (77.0)	535 (80.2)	1674 (79.0)
>=130 to 140	101 (14.3)	116 (15.5)	98 (14.7)	315 (14.9)
>=140	40 (5.7)	56 (7.5)	34 (5.1)	130 (6.1)
Diastolic blood pressure (mmHg)				
N	704	748	667	2119
Mean (SD)	71.85 (9.90)	73.48 (9.16)	72.03 (9.55)	72.48 (9.56)
Median	70.00	73.00	72.00	72.00
2.5; 97.5 percentiles	55.00; 91.00	59.00; 93.00	51.00; 90.00	55.00; 92.00
Min, Max	45.00; 111.00	45.00; 112.00	39.00; 110.00	39.00; 112.00
Diastolic blood pressure(mmHg), N(%)				
N	704	748	667	2119
<85	639 (90.8)	658 (88.0)	607 (91.0)	1904 (89.9)
>=85 to 90	36 (5.1)	52 (7.0)	41 (6.1)	129 (6.1)
>=90	29 (4.1)	38 (5.1)	19 (2.8)	86 (4.1)
Current anti-diabetic treatment at enrolment				
Basal insulin at enrolment, N(%)				
N	764	828	781	2373
Yes	764 (100.0)	828 (100.0)		1592 (67.1)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - FAS_MOTHER

	Insulin detemir		Other basal insulin		No basal insulin		Total	
No					781	(100.0)	781	(32.9)
Bolus insulin at enrolment, N(%)								
N	764		828		781		2373	
Yes	749	(98.0)	803	(97.0)	765	(98.0)	2317	(97.6)
No	15	(2.0)	25	(3.0)	16	(2.0)	56	(2.4)
Premix insulin at enrolment, N(%)								
N	764		828		781		2373	
Yes	1	(0.1)	2	(0.2)	15	(1.9)	18	(0.8)
No	763	(99.9)	826	(99.8)	766	(98.1)	2355	(99.2)
OAD at enrolment, N(%)								
N	764		828		781		2373	
Yes	39	(5.1)	35	(4.2)	10	(1.3)	84	(3.5)
No	725	(94.9)	793	(95.8)	771	(98.7)	2289	(96.5)
GLP-1 RA at enrolment, N(%)								
N	764		828		781		2373	
Yes					3	(0.4)	3	(0.1)
No	764	(100.0)	828	(100.0)	778	(99.6)	2370	(99.9)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

14.1.17 Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER

	Insulin detemir	Other basal insulin	Total
Number of subjects	727	730	1457
Demographic and socioeconomic information Country, N(%)			
N	727	730	1457
Croatia	238 (32.7)	47 (6.4)	285 (19.6)
Denmark	126 (17.3)	257 (35.2)	383 (26.3)
Finland	57 (7.8)	50 (6.8)	107 (7.3)
France	9 (1.2)	15 (2.1)	24 (1.6)
Germany	4 (0.6)	9 (1.2)	13 (0.9)
Greece	4 (0.6)	7 (1.0)	11 (0.8)
Ireland	28 (3.9)	31 (4.2)	59 (4.0)
Israel	53 (7.3)	8 (1.1)	61 (4.2)
Italy	15 (2.1)	21 (2.9)	36 (2.5)
Malaysia	5 (0.7)	14 (1.9)	19 (1.3)
Netherlands	11 (1.5)	6 (0.8)	17 (1.2)
Norway	4 (0.6)	20 (2.7)	24 (1.6)
Poland	19 (2.6)	38 (5.2)	57 (3.9)
Portugal	3 (0.4)	12 (1.6)	15 (1.0)
Romania	22 (3.0)	1 (0.1)	23 (1.6)
Spain	27 (3.7)	87 (11.9)	114 (7.8)
United Kingdom	102 (14.0)	107 (14.7)	209 (14.3)
Age			
N	727	730	1457
Mean (SD)	31.08 (5.05)	30.57 (5.33)	30.83 (5.19)
Median	31.00	30.00	31.00
2.5; 97.5 percentiles	21.00; 40.00	21.00; 41.00	21.00; 40.00
Min, Max	18.00; 44.00	17.00; 47.00	17.00; 47.00

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER

	Insulin detemir		Other basal insulin		Total	
Race, N(%)						
N	717		715		1432	
Asian	12	(1.7)	28	(3.9)	40	(2.8)
Black or African American	7	(1.0)	7	(1.0)	14	(1.0)
Native Hawaiian or other Pacific Islander			1	(0.1)	1	(<0.1)
White	688	(96.0)	649	(90.8)	1337	(93.4)
Other	10	(1.4)	30	(4.2)	40	(2.8)
Education, N(%)						
N	673		665		1338	
University degree	203	(30.2)	154	(23.2)	357	(26.7)
College degree	89	(13.2)	107	(16.1)	196	(14.6)
Graduate school	128	(19.0)	90	(13.5)	218	(16.3)
Technical school	47	(7.0)	48	(7.2)	95	(7.1)
High school	100	(14.9)	99	(14.9)	199	(14.9)
A levels	22	(3.3)	19	(2.9)	41	(3.1)
Intermediate school leaving certificate	19	(2.8)	44	(6.6)	63	(4.7)
Basic school leaving certificate	21	(3.1)	30	(4.5)	51	(3.8)
Primary school	6	(0.9)	16	(2.4)	22	(1.6)
No education	3	(0.4)	12	(1.8)	15	(1.1)
Other	35	(5.2)	46	(6.9)	81	(6.1)
Occupation, N(%)						
N	692		693		1385	
Managerial (employed or self-employed)	99	(14.3)	40	(5.8)	139	(10.0)
Professional and higher technical	127	(18.4)	126	(18.2)	253	(18.3)
Clerical or lower technical	76	(11.0)	63	(9.1)	139	(10.0)
Skilled worker	174	(25.1)	156	(22.5)	330	(23.8)
Semiskilled worker	37	(5.3)	53	(7.6)	90	(6.5)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER

	Insulin detemir		Other basal insulin		Total	
Unskilled worker	15	(2.2)	42	(6.1)	57	(4.1)
Student	26	(3.8)	43	(6.2)	69	(5.0)
Not working	106	(15.3)	128	(18.5)	234	(16.9)
Other	32	(4.6)	42	(6.1)	74	(5.3)
Tobacco , N(%)						
N	711		702		1413	
Never	558	(78.5)	519	(73.9)	1077	(76.2)
Previous	87	(12.2)	116	(16.5)	203	(14.4)
Current	66	(9.3)	67	(9.5)	133	(9.4)
Alcohol , N(%)						
N	699		686		1385	
Yes	7	(1.0)	8	(1.2)	15	(1.1)
No	692	(99.0)	678	(98.8)	1370	(98.9)
Obstetric history						
Number of previous pregnancies, N(%)						
N	727		730		1457	
0	229	(31.5)	260	(35.6)	489	(33.6)
1	268	(36.9)	247	(33.8)	515	(35.3)
2	114	(15.7)	116	(15.9)	230	(15.8)
3	59	(8.1)	58	(7.9)	117	(8.0)
4+	57	(7.8)	49	(6.7)	106	(7.3)
Number of previous live births, N(%)						
N	706		661		1367	
0	325	(46.0)	290	(43.9)	615	(45.0)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER

	Insulin detemir		Other basal insulin		Total	
1	283	(40.1)	276	(41.8)	559	(40.9)
2	74	(10.5)	77	(11.6)	151	(11.0)
3	13	(1.8)	17	(2.6)	30	(2.2)
4+	11	(1.6)	1	(0.2)	12	(0.9)
Previous Pregnancy Complications (Y/N), N(%)						
N	695		650		1345	
Yes	375	(54.0)	351	(54.0)	726	(54.0)
No	320	(46.0)	299	(46.0)	619	(46.0)
Previous pre-eclampsia, N(%)						
N	727		730		1457	
Yes	28	(3.9)	32	(4.4)	60	(4.1)
No	699	(96.1)	698	(95.6)	1397	(95.9)
Previous caesarean section, N(%)						
N	727		730		1457	
Yes	172	(23.7)	119	(16.3)	291	(20.0)
No	555	(76.3)	611	(83.7)	1166	(80.0)
Previous perinatal deaths, N(%)						
N	727		730		1457	
Yes	13	(1.8)	12	(1.6)	25	(1.7)
No	714	(98.2)	718	(98.4)	1432	(98.3)
Previous preterm delivery , N(%)						
N	727		730		1457	
Yes	47	(6.5)	55	(7.5)	102	(7.0)
No	680	(93.5)	675	(92.5)	1355	(93.0)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER

	Insulin detemir		Other basal insulin		Total	
Previous spontaneous abortion, N(%)						
N	727		730		1457	
Yes	185	(25.4)	162	(22.2)	347	(23.8)
No	542	(74.6)	568	(77.8)	1110	(76.2)
Previous malformations, N(%)						
N	727		730		1457	
Yes	14	(1.9)	15	(2.1)	29	(2.0)
No	713	(98.1)	715	(97.9)	1428	(98.0)
Previous minor malformations, N(%)						
N	727		730		1457	
Yes	2	(0.3)	6	(0.8)	8	(0.5)
No	725	(99.7)	724	(99.2)	1449	(99.5)
Previous major malformations, N(%)						
N	727		730		1457	
Yes	12	(1.7)	9	(1.2)	21	(1.4)
No	715	(98.3)	721	(98.8)	1436	(98.6)
Other pregnancy complications						
N	727		730		1457	
Yes	85	(11.7)	113	(15.5)	198	(13.6)
No	642	(88.3)	617	(84.5)	1259	(86.4)
Medical history						
Hypertension, N(%)						
N	727		729		1456	

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER

	Insulin detemir		Other basal insulin		Total	
Yes	64	(8.8)	60	(8.2)	124	(8.5)
No	663	(91.2)	669	(91.8)	1332	(91.5)
Epilepsy, N(%)						
N	725		729		1454	
Yes	10	(1.4)	12	(1.6)	22	(1.5)
No	715	(98.6)	717	(98.4)	1432	(98.5)
Thyroid disorder, N(%)						
N	726		727		1453	
Yes	174	(24.0)	177	(24.3)	351	(24.2)
No	552	(76.0)	550	(75.7)	1102	(75.8)
Asthma, N(%)						
N	725		729		1454	
Yes	32	(4.4)	49	(6.7)	81	(5.6)
No	693	(95.6)	680	(93.3)	1373	(94.4)
Heart disease, N(%)						
N	726		728		1454	
Yes	3	(0.4)	8	(1.1)	11	(0.8)
No	723	(99.6)	720	(98.9)	1443	(99.2)
Psychiatric disorder, N(%)						
N	727		728		1455	
Yes	46	(6.3)	65	(8.9)	111	(7.6)
No	681	(93.7)	663	(91.1)	1344	(92.4)
Inheritable diseases, N(%)						

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER

	Insulin detemir	Other basal insulin	Total
N	722	724	1446
Yes	28 (3.9)	26 (3.6)	54 (3.7)
No	694 (96.1)	698 (96.4)	1392 (96.3)
Diabetes history			
Type of DM, N(%)			
N	727	730	1457
T1DM	595 (81.8)	654 (89.6)	1249 (85.7)
T2DM	132 (18.2)	76 (10.4)	208 (14.3)
Diabetes duration			
N	724	723	1447
Mean (SD)	13.07 (8.11)	13.61 (8.52)	13.34 (8.32)
Median	12.00	13.00	12.00
2.5; 97.5 percentiles	2.00; 30.00	2.00; 30.00	2.00; 30.00
Min, Max	1.00; 35.00	1.00; 38.00	1.00; 38.00
Diabetes duration, N(%)			
N	724	723	1447
<5 years	124 (17.1)	130 (18.0)	254 (17.6)
>= 5 years	600 (82.9)	593 (82.0)	1193 (82.4)
History of diabetes complications, N(%)			
N	726	728	1454
Yes	184 (25.3)	171 (23.5)	355 (24.4)
No	542 (74.7)	557 (76.5)	1099 (75.6)
History of microvascular complications, N(%)			

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER

	Insulin detemir		Other basal insulin		Total	
N	726		726		1452	
Yes	184	(25.3)	171	(23.6)	355	(24.4)
No	542	(74.7)	555	(76.4)	1097	(75.6)
History of macrovascular complications, N(%)						
N	725		727		1452	
Yes	1	(0.1)	1	(0.1)	2	(0.1)
No	724	(99.9)	726	(99.9)	1450	(99.9)
History of retinopathy, N(%)						
N	725		723		1448	
Yes	155	(21.4)	158	(21.9)	313	(21.6)
No	570	(78.6)	565	(78.1)	1135	(78.4)
History of neuropathy, N(%)						
N	725		723		1448	
Yes	28	(3.9)	8	(1.1)	36	(2.5)
No	697	(96.1)	715	(98.9)	1412	(97.5)
History of nephropathy, N(%)						
N	724		725		1449	
Yes	34	(4.7)	30	(4.1)	64	(4.4)
No	690	(95.3)	695	(95.9)	1385	(95.6)
History of macroangiopathy (including peripheral vascular disease), N(%)						
N	725		725		1450	
Yes	1	(0.1)	1	(0.1)	2	(0.1)
No	724	(99.9)	724	(99.9)	1448	(99.9)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER

	Insulin detemir	Other basal insulin	Total
History of unstable angina, N(%)			
N	720	726	1446
Yes		1 (0.1)	1 (<0.1)
No	720 (100.0)	725 (99.9)	1445 (99.9)
History of heart failure, N(%)			
N	707	725	1432
No	707 (100.0)	725 (100.0)	1432 (100.0)
Current pregnancy			
Gestational age at enrolment (weeks)			
N	723	724	1447
Mean (SD)	8.73 (2.45)	8.83 (2.55)	8.78 (2.50)
Median	8.00	8.00	8.00
2.5; 97.5 percentiles	5.00; 14.00	5.00; 15.00	5.00; 14.00
Min, Max	4.00; 16.00	3.00; 16.00	3.00; 16.00
Gestational age at enrolment (weeks), N(%)			
N	723	724	1447
<7	146 (20.2)	142 (19.6)	288 (19.9)
>=7 - 12	473 (65.4)	472 (65.2)	945 (65.3)
>=12 - 16	104 (14.4)	110 (15.2)	214 (14.8)
Folic acid taken before and during first trimester, N(%)			
N	718	723	1441
Yes	459 (63.9)	579 (80.1)	1038 (72.0)
No	259 (36.1)	144 (19.9)	403 (28.0)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER

	Insulin detemir	Other basal insulin	Total
HbA1c, anthropometric measurements and vital signs at enrolment			
HbA1c			
N	690	689	1379
Mean (SD)	6.95 (1.26)	7.15 (1.39)	7.05 (1.33)
Median	6.71	6.82	6.80
2.5; 97.5 percentiles	5.20; 10.29	5.35; 10.50	5.20; 10.39
Min, Max	4.40; 13.90	4.71; 14.50	4.40; 14.50
HbA1c (<7%), N(%)			
N	690	689	1379
Yes	424 (61.4)	390 (56.6)	814 (59.0)
No	266 (38.6)	299 (43.4)	565 (41.0)
HbA1c (<6.5%), N(%)			
N	690	689	1379
Yes	276 (40.0)	255 (37.0)	531 (38.5)
No	414 (60.0)	434 (63.0)	848 (61.5)
HbA1c%), N(%)			
N	690	689	1379
<5.5	43 (6.2)	32 (4.6)	75 (5.4)
>= 5.5 to 6.0	101 (14.6)	91 (13.2)	192 (13.9)
>=6.0 to 6.5	132 (19.1)	132 (19.2)	264 (19.1)
>=6.5 to 7.0	148 (21.4)	135 (19.6)	283 (20.5)
>=7.0 to 7.5	84 (12.2)	75 (10.9)	159 (11.5)
>=7.5 to 8.0	62 (9.0)	58 (8.4)	120 (8.7)
>=8.0 to 8.5	42 (6.1)	61 (8.9)	103 (7.5)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER

	Insulin detemir	Other basal insulin	Total
>=8.5 to 9.0	26 (3.8)	35 (5.1)	61 (4.4)
>=9.0 to 9.5	19 (2.8)	29 (4.2)	48 (3.5)
>=9.5	33 (4.8)	41 (6.0)	74 (5.4)
Weight (kg)			
N	703	705	1408
Mean (SD)	71.06 (16.10)	73.20 (16.46)	72.13 (16.31)
Median	67.00	69.80	68.50
2.5; 97.5 percentiles	50.80; 115.00	50.50; 115.80	50.60; 115.00
Min, Max	43.00; 150.00	44.00; 141.60	43.00; 150.00
BMI (kg/m2)			
N	701	699	1400
Mean (SD)	25.77 (5.73)	26.62 (5.65)	26.19 (5.70)
Median	24.30	25.40	24.70
2.5; 97.5 percentiles	18.70; 40.80	19.00; 41.90	18.80; 41.05
Min, Max	16.30; 52.50	16.40; 49.00	16.30; 52.50
BMI (kg/m2)%), N(%)			
N	701	699	1400
<18.5	12 (1.7)	8 (1.1)	20 (1.4)
>= 18.5 to 25.0	389 (55.5)	325 (46.5)	714 (51.0)
>=25.0 to 30.0	171 (24.4)	210 (30.0)	381 (27.2)
>=30.0 to 35.0	71 (10.1)	93 (13.3)	164 (11.7)
>=35.0 to 40.0	37 (5.3)	39 (5.6)	76 (5.4)
>=40.0	21 (3.0)	24 (3.4)	45 (3.2)
Systolic blood pressure (mmHg)			
N	675	661	1336

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER

	Insulin detemir	Other basal insulin	Total
Mean (SD)	117.41 (13.50)	119.48 (13.91)	118.44 (13.73)
Median	119.00	120.00	119.50
2.5; 97.5 percentiles	90.00; 145.00	95.00; 149.00	90.00; 148.00
Min, Max	80.00; 183.00	83.00; 188.00	80.00; 188.00
Systolic blood pressure (mmHg)%), N(%)			
N	675	661	1336
<130	542 (80.3)	505 (76.4)	1047 (78.4)
>=130 to 140	100 (14.8)	105 (15.9)	205 (15.3)
>=140	33 (4.9)	51 (7.7)	84 (6.3)
Diastolic blood pressure (mmHg)			
N	675	661	1336
Mean (SD)	71.95 (9.89)	73.70 (9.07)	72.82 (9.53)
Median	70.00	73.00	72.00
2.5; 97.5 percentiles	55.00; 92.00	60.00; 93.00	58.00; 92.00
Min, Max	45.00; 111.00	45.00; 112.00	45.00; 112.00
Diastolic blood pressure(mmHg), N(%)			
N	675	661	1336
<85	613 (90.8)	579 (87.6)	1192 (89.2)
>=85 to 90	34 (5.0)	48 (7.3)	82 (6.1)
>=90	28 (4.1)	34 (5.1)	62 (4.6)
Current anti-diabetic treatment at enrolment			
Basal insulin at enrolment, N(%)			
N	727	730	1457
Yes	727 (100.0)	730 (100.0)	1457 (100.0)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

Demographics and baseline characteristics - basal insulin treatment group at enrolment - summary - MOTHER

	Insulin detemir		Other basal insulin		Total	
Bolus insulin at enrolment, N(%)						
N	727		730		1457	
Yes	714	(98.2)	713	(97.7)	1427	(97.9)
No	13	(1.8)	17	(2.3)	30	(2.1)
Premix insulin at enrolment, N(%)						
N	727		730		1457	
No	727	(100.0)	730	(100.0)	1457	(100.0)
OAD at enrolment, N(%)						
N	727		730		1457	
Yes	36	(5.0)	32	(4.4)	68	(4.7)
No	691	(95.0)	698	(95.6)	1389	(95.3)
GLP-1 RA at enrolment, N(%)						
N	727		730		1457	
No	727	(100.0)	730	(100.0)	1457	(100.0)

N: Number of patients, T2DM: Type 2 diabetes mellitus, %: Percentage of patients, BMI: Body mass index (kg/m^2), T1DM: Type 1 diabetes mellitus, SD: Standard deviation

14.1.18 Foetus characteristics - basal insulin treatment group at enrolment - summary – FAS_FOETUS

	Insulin detemir	Other basal insulin	No basal insulin	Total
Number of subjects	773	828	795	2396
Abortion, N (%)				
N	773	828	795	2396
Yes	62 (8.0)	67 (8.1)	64 (8.1)	193 (8.1)
No	711 (92.0)	761 (91.9)	731 (91.9)	2203 (91.9)
Spontaneous abortion, N (%)				
N	773	828	795	2396
Yes	42 (5.4)	46 (5.6)	34 (4.3)	122 (5.1)
No	731 (94.6)	782 (94.4)	761 (95.7)	2274 (94.9)
Induced abortion, N (%)				
N	773	828	795	2396
Yes	20 (2.6)	21 (2.5)	30 (3.8)	71 (3.0)
No	753 (97.4)	807 (97.5)	765 (96.2)	2325 (97.0)
Perinatal death, N (%)				
N	773	828	795	2396
Yes	6 (0.8)	13 (1.6)	12 (1.5)	31 (1.3)
No	767 (99.2)	815 (98.4)	783 (98.5)	2365 (98.7)
Neonatal death, N (%)				
N	754	810	768	2332
Yes	1 (0.1)			1 (<0.1)
No	753 (99.9)	810 (100.0)	768 (100.0)	2331 (100.0)
Liveborn, N (%)				
N	773	828	795	2396
Yes	709 (91.7)	754 (91.1)	723 (90.9)	2186 (91.2)
No	64 (8.3)	74 (8.9)	72 (9.1)	210 (8.8)

N: Number of patients, %: Percentage of patients

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14.1.19 Foetus characteristics - basal insulin treatment group at enrolment - summary – FOETUS

	Insulin detemir	Other basal insulin	Total
Number of subjects	741	740	1481
Abortion, N (%)			
N	741	740	1481
Yes	57 (7.7)	64 (8.6)	121 (8.2)
No	684 (92.3)	676 (91.4)	1360 (91.8)
Spontaneous abortion, N (%)			
N	741	740	1481
Yes	40 (5.4)	43 (5.8)	83 (5.6)
No	701 (94.6)	697 (94.2)	1398 (94.4)
Induced abortion, N (%)			
N	741	740	1481
Yes	17 (2.3)	21 (2.8)	38 (2.6)
No	724 (97.7)	719 (97.2)	1443 (97.4)
Perinatal death, N (%)			
N	741	740	1481
Yes	6 (0.8)	13 (1.8)	19 (1.3)
No	735 (99.2)	727 (98.2)	1462 (98.7)
Neonatal death, N (%)			
N	723	726	1449
Yes	1 (0.1)		1 (0.1)
No	722 (99.9)	726 (100.0)	1448 (99.9)
Liveborn, N (%)			
N	741	740	1481
Yes	682 (92.0)	669 (90.4)	1351 (91.2)
No	59 (8.0)	71 (9.6)	130 (8.8)

N: Number of patients, %: Percentage of patients

14.1.20 Foetus characteristics – basal insulin treatment group at enrolment - summary – FAS_LIVEBORN

	Insulin detemir	Other basal insulin	No basal insulin	Total
Number of subjects	709	754	723	2186
Sex, N (%)				
N	709	753	722	2184
Female	339 (47.8)	350 (46.5)	348 (48.2)	1037 (47.5)
Male	370 (52.2)	403 (53.5)	374 (51.8)	1147 (52.5)
Head circumference cm				
N	657	683	638	1978
Mean SD	34.24 (1.93)	34.23 (2.06)	34.51 (1.89)	34.32 (1.97)
Median	34.00	34.00	35.00	34.50
2.5; 97.5% percentiles	31.00 ; 38.00	30.00 ; 38.00	30.00 ; 38.00	30.00 ; 38.00
Min Max	21.00 ; 39.00	20.70 ; 42.00	25.70 ; 39.00	20.70 ; 42.00
Birth weight g				
N	709	753	721	2183
Mean SD	3430.24 (688.91)	3425.66 (678.05)	3497.59 (702.21)	3450.90 (690.10)
Median	3484.00	3490.00	3560.00	3510.00
2.5; 97.5% percentiles	1750.00 ; 4670.00	1825.00 ; 4610.00	1620.00 ; 4690.00	1790.00 ; 4651.00
Min Max	550.00 ; 5370.00	540.00 ; 5030.00	600.00 ; 5320.00	540.00 ; 5370.00
Length at birth cm				
N	598	652	589	1839
Mean SD	49.93 (3.41)	50.33 (3.29)	50.80 (3.66)	50.35 (3.47)
Median	50.00	51.00	51.00	50.40
2.5; 97.5% percentiles	42.50 ; 56.00	42.00 ; 56.00	42.50 ; 58.00	42.30 ; 57.00
Min Max	31.00 ; 64.00	28.00 ; 60.00	36.20 ; 66.00	28.00 ; 66.00
Apgar score at 5 minutes				
N	700	727	713	2140

N: Number of patients, %: Percentage of patients, SD: Standard deviation

Foetus characteristics – basal insulin treatment group at enrolment - summary – FAS_LIVEBORN

	Insulin detemir	Other basal insulin	No basal insulin	Total
Mean SD	9.45 (1.08)	9.48 (0.87)	9.42 (1.20)	9.45 (1.06)
Median	10.00	10.00	10.00	10.00
2.5; 97.5% percentiles	6.00 ; 10.00	7.00 ; 10.00	6.00 ; 10.00	6.00 ; 10.00
Min Max	0.00 ; 10.00	4.00 ; 10.00	1.00 ; 10.00	0.00 ; 10.00
Apgar score at 5 minutes, N (%)				
N	700	727	713	2140
0-3 points	4 (0.6)		6 (0.8)	10 (0.5)
4-6 points	14 (2.0)	13 (1.8)	20 (2.8)	47 (2.2)
7-10 points	682 (97.4)	714 (98.2)	687 (96.4)	2083 (97.3)
Admission to intensive care for more than 48 hours, N (%)				
N	692	733	703	2128
Yes	109 (15.8)	149 (20.3)	124 (17.6)	382 (18.0)
No	583 (84.2)	584 (79.7)	579 (82.4)	1746 (82.0)
Arterial umbilical cord pH				
N	568	518	544	1630
Mean SD	7.24 (0.09)	7.23 (0.09)	7.23 (0.09)	7.23 (0.09)
Median	7.25	7.23	7.23	7.24
2.5; 97.5% percentiles	7.04 ; 7.38	7.03 ; 7.37	7.03 ; 7.39	7.03 ; 7.38
Min Max	6.77 ; 7.42	6.80 ; 7.44	6.86 ; 7.45	6.77 ; 7.45
Respiratory distress syndrome, N (%)				
N	695	745	711	2151
Yes	56 (8.1)	101 (13.6)	98 (13.8)	255 (11.9)
No	639 (91.9)	644 (86.4)	613 (86.2)	1896 (88.1)
Neonatal hypoglycaemia 24 hrs, N (%)				

N: Number of patients, %: Percentage of patients, SD: Standard deviation

Foetus characteristics - basal insulin treatment group at enrolment - summary - FAS_LIVEBORN

	Insulin detemir	Other basal insulin	No basal insulin	Total
N	690	727	700	2117
Yes	97 (14.1)	139 (19.1)	138 (19.7)	374 (17.7)
No	593 (85.9)	588 (80.9)	562 (80.3)	1743 (82.3)
Neonatal hypoglycaemia 48 hrs, N (%)				
N	672	701	674	2047
Yes	26 (3.9)	46 (6.6)	37 (5.5)	109 (5.3)
No	646 (96.1)	655 (93.4)	637 (94.5)	1938 (94.7)
Gestational week at delivery				
N	708	747	723	2178
Mean SD	36.94 (1.98)	36.88 (2.06)	36.67 (2.03)	36.83 (2.03)
Median	37.50	37.00	37.00	37.00
2.5; 97.5% percentiles	32.00 ; 39.00	32.00 ; 39.00	32.00 ; 39.00	32.00 ; 39.00
Min Max	26.00 ; 40.00	24.00 ; 41.00	22.00 ; 41.00	22.00 ; 41.00
Multiple birth, N (%)				
N	709	754	723	2186
Yes	30 (4.2)	24 (3.2)	36 (5.0)	90 (4.1)
No	679 (95.8)	730 (96.8)	687 (95.0)	2096 (95.9)
Spontaneous onset of labour, N (%)				
N	703	745	719	2167
Yes	143 (20.3)	154 (20.7)	157 (21.8)	454 (21.0)
No	560 (79.7)	591 (79.3)	562 (78.2)	1713 (79.0)
Induction of labour, N (%)				
N	702	742	716	2160
Yes	270 (38.5)	386 (52.0)	366 (51.1)	1022 (47.3)
No	432 (61.5)	356 (48.0)	350 (48.9)	1138 (52.7)

N: Number of patients, %: Percentage of patients, SD: Standard deviation

Foetus characteristics – basal insulin treatment group at enrolment - summary – FAS_LIVEBORN

	Insulin detemir	Other basal insulin	No basal insulin	Total
Delivery type, N (%)				
N	708	753	722	2183
Caesarean section	487 (68.8)	444 (59.0)	417 (57.8)	1348 (61.7)
Vaginal birth	221 (31.2)	309 (41.0)	305 (42.2)	835 (38.3)
Caesarean section, N (%)				
N	487	444	417	1348
Non planned caesarean section	189 (38.8)	225 (50.7)	205 (49.2)	619 (45.9)
Planned caesarean section	298 (61.2)	219 (49.3)	212 (50.8)	729 (54.1)
Major congenital Malformation, N (%)				
N	707	753	723	2183
Yes	16 (2.3)	17 (2.3)	13 (1.8)	46 (2.1)
No	691 (97.7)	736 (97.7)	710 (98.2)	2137 (97.9)
Minor congenital Malformation, N (%)				
N	707	753	723	2183
Yes	54 (7.6)	80 (10.6)	89 (12.3)	223 (10.2)
No	653 (92.4)	673 (89.4)	634 (87.7)	1960 (89.8)
Pre-term delivery, N (%)				
N	708	747	723	2178
Yes	198 (28.0)	220 (29.5)	255 (35.3)	673 (30.9)
No	510 (72.0)	527 (70.5)	468 (64.7)	1505 (69.1)
Foetal Macrosomia, N (%)				
N	709	753	721	2183
Yes	127 (17.9)	134 (17.8)	163 (22.6)	424 (19.4)
No	582 (82.1)	619 (82.2)	558 (77.4)	1759 (80.6)

N: Number of patients, %: Percentage of patients, SD: Standard deviation

Foetus characteristics – basal insulin treatment group at enrolment - summary – FAS_LIVEBORN

	Insulin detemir	Other basal insulin	No basal insulin	Total
Large-for gestational age, N (%)				
N	675	715	705	2095
Yes	315 (46.7)	367 (51.3)	404 (57.3)	1086 (51.8)
No	360 (53.3)	348 (48.7)	301 (42.7)	1009 (48.2)

N: Number of patients, %: Percentage of patients, SD: Standard deviation

14.1.21 Foetus characteristics - basal insulin treatment group at enrolment - summary – LIVEBORN

	Insulin detemir	Other basal insulin	Total
Number of subjects	682	669	1351
Sex, N (%)			
N	682	668	1350
Female	326 (47.8)	313 (46.9)	639 (47.3)
Male	356 (52.2)	355 (53.1)	711 (52.7)
Head circumference cm			
N	635	609	1244
Mean SD	34.26 (1.93)	34.26 (2.03)	34.26 (1.98)
Median	34.00	34.00	34.00
2.5; 97.5% percentiles	31.00 ; 38.00	30.00 ; 37.50	30.00 ; 38.00
Min Max	21.00 ; 39.00	20.70 ; 42.00	20.70 ; 42.00
Birth weight g			
N	682	668	1350
Mean SD	3438.38 (688.21)	3430.20 (681.97)	3434.33 (684.89)
Median	3492.00	3505.50	3500.00
2.5; 97.5% percentiles	1870.00 ; 4670.00	1790.00 ; 4600.00	1820.00 ; 4630.00
Min Max	550.00 ; 5370.00	540.00 ; 5030.00	540.00 ; 5370.00
Length at birth cm			
N	579	580	1159
Mean SD	49.99 (3.40)	50.43 (3.32)	50.21 (3.37)
Median	50.00	51.00	50.00
2.5; 97.5% percentiles	43.00 ; 56.00	42.00 ; 56.00	42.20 ; 56.00
Min Max	31.00 ; 64.00	28.00 ; 60.00	28.00 ; 64.00
Apgar score at 5 minutes			
N	673	643	1316

N: Number of patients, %: Percentage of patients, SD: Standard deviation

Foetus characteristics - basal insulin treatment group at enrolment - summary – LIVEBORN

	Insulin detemir	Other basal insulin	Total
Mean SD	9.45 (1.10)	9.48 (0.87)	9.47 (0.99)
Median	10.00	10.00	10.00
2.5; 97.5% percentiles	6.00 ; 10.00	7.00 ; 10.00	7.00 ; 10.00
Min Max	0.00 ; 10.00	4.00 ; 10.00	0.00 ; 10.00
Apgar score at 5 minutes, N (%)			
N	673	643	1316
0-3 points	4 (0.6)		4 (0.3)
4-6 points	14 (2.1)	11 (1.7)	25 (1.9)
7-10 points	655 (97.3)	632 (98.3)	1287 (97.8)
Admission to intensive care for more than 48 hours, N (%)			
N	667	649	1316
Yes	104 (15.6)	134 (20.6)	238 (18.1)
No	563 (84.4)	515 (79.4)	1078 (81.9)
Arterial umbilical cord pH			
N	547	459	1006
Mean SD	7.24 (0.09)	7.23 (0.08)	7.23 (0.09)
Median	7.25	7.23	7.24
2.5; 97.5% percentiles	7.03 ; 7.38	7.05 ; 7.37	7.04 ; 7.38
Min Max	6.77 ; 7.42	6.89 ; 7.44	6.77 ; 7.44
Respiratory distress syndrome, N (%)			
N	669	661	1330
Yes	54 (8.1)	87 (13.2)	141 (10.6)
No	615 (91.9)	574 (86.8)	1189 (89.4)
Neonatal hypoglycaemia 24 hrs, N (%)			

N: Number of patients, %: Percentage of patients, SD: Standard deviation

Foetus characteristics - basal insulin treatment group at enrolment - summary – LIVEBORN

	Insulin detemir	Other basal insulin	Total
N	664	646	1310
Yes	92 (13.9)	124 (19.2)	216 (16.5)
No	572 (86.1)	522 (80.8)	1094 (83.5)
Neonatal hypoglycaemia 48 hrs, N (%)			
N	647	623	1270
Yes	24 (3.7)	42 (6.7)	66 (5.2)
No	623 (96.3)	581 (93.3)	1204 (94.8)
Gestational week at delivery			
N	681	664	1345
Mean SD	36.99 (1.96)	36.91 (2.09)	36.95 (2.03)
Median	38.00	37.00	37.00
2.5; 97.5% percentiles	32.00 ; 39.00	31.00 ; 39.00	31.00 ; 39.00
Min Max	26.00 ; 40.00	24.00 ; 41.00	24.00 ; 41.00
Multiple birth, N (%)			
N	682	669	1351
Yes	26 (3.8)	20 (3.0)	46 (3.4)
No	656 (96.2)	649 (97.0)	1305 (96.6)
Spontaneous onset of labour, N (%)			
N	676	660	1336
Yes	136 (20.1)	141 (21.4)	277 (20.7)
No	540 (79.9)	519 (78.6)	1059 (79.3)
Induction of labour, N (%)			
N	675	658	1333
Yes	257 (38.1)	340 (51.7)	597 (44.8)
No	418 (61.9)	318 (48.3)	736 (55.2)

N: Number of patients, %: Percentage of patients, SD: Standard deviation

Foetus characteristics - basal insulin treatment group at enrolment - summary – LIVEBORN

	Insulin detemir	Other basal insulin	Total
Delivery type, N (%)			
N	681	668	1349
Caesarean section	470 (69.0)	389 (58.2)	859 (63.7)
Vaginal birth	211 (31.0)	279 (41.8)	490 (36.3)
Caesarean section, N (%)			
N	470	389	859
Non planned caesarean section	178 (37.9)	192 (49.4)	370 (43.1)
Planned caesarean section	292 (62.1)	197 (50.6)	489 (56.9)
Major congenital Malformation, N (%)			
N	680	668	1348
Yes	15 (2.2)	17 (2.5)	32 (2.4)
No	665 (97.8)	651 (97.5)	1316 (97.6)
Minor congenital Malformation, N (%)			
N	680	668	1348
Yes	49 (7.2)	68 (10.2)	117 (8.7)
No	631 (92.8)	600 (89.8)	1231 (91.3)
Pre-term delivery, N (%)			
N	681	664	1345
Yes	182 (26.7)	185 (27.9)	367 (27.3)
No	499 (73.3)	479 (72.1)	978 (72.7)
Foetal Macrosomia, N (%)			
N	682	668	1350
Yes	125 (18.3)	118 (17.7)	243 (18.0)
No	557 (81.7)	550 (82.3)	1107 (82.0)

N: Number of patients, %: Percentage of patients, SD: Standard deviation

Foetus characteristics - basal insulin treatment group at enrolment - summary – LIVEBORN

	Insulin detemir	Other basal insulin	Total
Large-for gestational age, N (%)			
N	650	635	1285
Yes	305 (46.9)	326 (51.3)	631 (49.1)
No	345 (53.1)	309 (48.7)	654 (50.9)

N: Number of patients, %: Percentage of patients, SD: Standard deviation

14.1.22 Infant characteristics - basal insulin treatment group at enrolment - summary – FAS_INFANT

	Insulin detemir	Other basal insulin	No basal insulin	Total
Number of subjects	664	705	674	2043
Height at 1-month visit (cm)				
N	588	600	588	1776
Mean (SD)	54.42 (3.47)	54.40 (3.80)	54.79 (3.99)	54.54 (3.76)
Median	54.50	54.25	54.85	54.50
2.5; 97.5 percentiles	47.00; 61.00	46.00; 61.00	47.00; 62.00	47.00; 61.00
Min; Max	37.00; 68.50	28.00; 70.50	37.60; 92.00	28.00; 92.00
Weight at 1-month visit (g)				
N	627	660	631	1918
Mean (SD)	4392.09 (744.40)	4347.31 (810.58)	4351.59 (778.98)	4363.35 (778.87)
Median	4400.00	4400.00	4350.00	4399.80
2.5; 97.5 percentiles	2870.00; 5900.00	2620.00; 5800.00	2800.00; 6000.00	2750.00; 5900.00
Min; Max	1920.00; 7700.00	868.00; 8100.00	1325.00; 7400.00	868.00; 8100.00
Previous lactation (exclusive and/or partial) at 1-year visit, N(%)				
N	663	699	669	2031
Yes	541 (81.6)	586 (83.8)	585 (87.4)	1712 (84.3)
No	122 (18.4)	113 (16.2)	84 (12.6)	319 (15.7)

N: Number of patients, %: Percentage of patients, SD: Standard deviation

Infant characteristics - basal insulin treatment group at enrolment - summary – FAS_INFANT

	Insulin detemir	Other basal insulin	No basal insulin	Total
Height at 1-year visit (cm)				
N	599	627	609	1835
Mean (SD)	76.49 (4.72)	76.32 (4.29)	76.47 (4.26)	76.43 (4.42)
Median	76.00	76.00	76.00	76.00
2.5; 97.5 percentiles	68.00; 86.50	68.50; 84.00	69.00; 86.00	68.50; 86.00
Min; Max	58.00; 98.00	42.30; 91.00	45.50; 93.00	42.30; 98.00
Weight at 1-year visit (g)				
N	613	654	625	1892
Mean (SD)	10096.82 (1323.38)	9969.50 (1372.17)	9917.10 (1309.26)	9993.44 (1337.24)
Median	10000.00	9900.00	9900.00	9900.00
2.5; 97.5 percentiles	7600.00; 12900.00	7400.00; 13000.00	7500.00; 12800.00	7500.00; 12900.00
Min; Max	6060.00; 15000.00	5100.00; 14800.00	5100.00; 15000.00	5100.00; 15000.00
Diabetes mellitus at 1-year visit, N (%)				
N	657	702	664	2023
Yes	2 (0.3)	2 (0.3)	1 (0.2)	5 (0.2)
No	655 (99.7)	700 (99.7)	663 (99.8)	2018 (99.8)
Change of major congenital malformations, N (%)				
N	647	682	658	1987
No change	8 (1.2)	10 (1.5)	7 (1.1)	25 (1.3)
Progression	2 (0.3)		1 (0.2)	3 (0.2)
Regression	2 (0.3)	5 (0.7)	3 (0.5)	10 (0.5)
No major congenital malformation	635 (98.1)	667 (97.8)	647 (98.3)	1949 (98.1)

N: Number of patients, %: Percentage of patients, SD: Standard deviation

14.1.23 Infant characteristics - basal insulin treatment group at enrolment - summary – INFANT

	Insulin detemir	Other basal insulin	Total
Number of subjects	638	630	1268
Height at 1-month visit (cm)			
N	568	538	1106
Mean (SD)	54.43 (3.50)	54.54 (3.81)	54.48 (3.65)
Median	54.50	54.50	54.50
2.5; 97.5 percentiles	47.00; 61.00	46.00; 61.00	46.00; 61.00
Min; Max	37.00; 68.50	28.00; 70.50	28.00; 70.50
Weight at 1-month visit (g)			
N	604	590	1194
Mean (SD)	4395.62 (750.25)	4350.29 (816.56)	4373.22 (783.71)
Median	4399.90	4400.00	4400.00
2.5; 97.5 percentiles	2870.00; 5900.00	2600.00; 5800.00	2720.00; 5820.00
Min; Max	1920.00; 7700.00	868.00; 8100.00	868.00; 8100.00
Previous lactation (exclusive and/or partial) at 1-year visit, N(%)			
N	637	625	1262
Yes	521 (81.8)	524 (83.8)	1045 (82.8)
No	116 (18.2)	101 (16.2)	217 (17.2)

N: Number of patients, %: Percentage of patients, SD: Standard deviation

Infant characteristics - basal insulin treatment group at enrolment - summary – INFANT

	Insulin detemir	Other basal insulin	Total
Height at 1-year visit (cm)			
N	581	558	1139
Mean (SD)	76.52 (4.76)	76.34 (4.28)	76.43 (4.53)
Median	76.00	76.00	76.00
2.5; 97.5 percentiles	68.50; 86.50	68.50; 84.00	68.50; 86.00
Min; Max	58.00; 98.00	42.30; 91.00	42.30; 98.00
Weight at 1-year visit (g)			
N	593	582	1175
Mean (SD)	10103.66 (1318.76)	9975.69 (1356.47)	10040.28 (1338.53)
Median	10000.00	9900.00	10000.00
2.5; 97.5 percentiles	7600.00; 12900.00	7500.00; 12800.00	7560.00; 12900.00
Min; Max	6060.00; 15000.00	5100.00; 14800.00	5100.00; 15000.00
Diabetes mellitus at 1-year visit, N (%)			
N	632	627	1259
Yes	2 (0.3)	2 (0.3)	4 (0.3)
No	630 (99.7)	625 (99.7)	1255 (99.7)
Change of major congenital malformations, N (%)			
N	622	609	1231
No change	7 (1.1)	10 (1.6)	17 (1.4)
Progression	2 (0.3)		2 (0.2)
Regression	2 (0.3)	5 (0.8)	7 (0.6)
No major congenital malformation	611 (98.2)	594 (97.5)	1205 (97.9)

N: Number of patients, %: Percentage of patients, SD: Standard deviation

14.1.24 HbA1c, hypoglycaemia, and pre-eclampsia during pregnancy – summary – FAS_MOTHER analysis set

	Insulin detemir N=764	Other basal insulin N=828	No basal insulin N=781	Total N=2373
HbA1c (%) at enrolment				
N	724	777	737	2238
Mean (SD)	7.00 (1.30)	7.19 (1.42)	6.81 (0.94)	7.01 (1.25)
Median	6.73	6.82	6.70	6.73
2.5; 97.5 percentiles	5.20; 10.50	5.35; 10.60	5.35; 9.10	5.30; 10.20
Min; Max	4.40; 13.90	4.71; 14.50	4.70; 13.90	4.40; 14.50
HbA1c (%) at conception (GW=2)				
N	281	293	338	912
Mean (SD)	7.20 (1.42)	7.34 (1.46)	6.94 (1.06)	7.15 (1.32)
Median	6.90	7.00	6.80	6.90
2.5; 97.5 percentiles	5.35; 10.90	5.44; 11.03	5.30; 9.60	5.40; 10.57
Min; Max	4.99; 13.90	4.80; 14.05	4.80; 13.90	4.80; 14.05
HbA1c (%) at end of first trimester (GW=12)				
N	700	779	727	2206
Mean (SD)	6.56 (1.11)	6.73 (1.20)	6.45 (0.83)	6.59 (1.07)
Median	6.38	6.50	6.40	6.40
2.5; 97.5 percentiles	4.90; 9.10	5.10; 9.90	5.17; 8.37	5.08; 9.10
Min; Max	4.40; 11.90	4.60; 14.50	4.50; 12.70	4.40; 14.50
HbA1c (%) at end of second trimester (GW=28)				
N	674	729	695	2098
Mean (SD)	6.12 (0.86)	6.24 (0.91)	6.23 (0.73)	6.20 (0.84)
Median	6.00	6.08	6.20	6.10
2.5; 97.5 percentiles	4.70; 8.10	4.90; 8.40	4.90; 7.90	4.90; 8.10
Min; Max	4.10; 10.66	3.98; 11.70	4.10; 9.38	3.98; 11.70
HbA1c (%) at end of third trimester (GW=40)				
N	358	460	387	1205
Mean (SD)	6.28 (0.83)	6.22 (0.76)	6.29 (0.71)	6.26 (0.76)
Median	6.27	6.15	6.27	6.18
2.5; 97.5 percentiles	5.00; 8.40	5.08; 7.80	5.10; 7.73	5.08; 7.91
Min; Max	4.20; 11.85	4.60; 11.12	4.60; 9.10	4.20; 11.85
HbA1c (%) at delivery				
N	747	795	762	2304
Mean (SD)	6.34 (1.04)	6.42 (0.99)	6.36 (0.86)	6.37 (0.97)
Median	6.20	6.27	6.27	6.27
2.5; 97.5 percentiles	4.90; 8.83	5.00; 8.74	5.00; 8.28	4.90; 8.74
Min; Max	4.10; 12.20	3.98; 11.70	4.10; 12.70	3.98; 12.70
Major hypoglycaemia during pregnancy, N (%)				
N	732	792	761	2285
Yes	48 (6.6)	80 (10.1)	63 (8.3)	191 (8.4)
No	684 (93.4)	712 (89.9)	698 (91.7)	2094 (91.6)
Pre-eclampsia during pregnancy, N (%)				
N	735	796	764	2295
Yes	49 (6.7)	80 (10.1)	85 (11.1)	214 (9.3)

GW: Gestational week, N: Number of patients, %: Percentage of patients, SD: Standard deviation

HbA1c, hypoglycaemia, and pre-eclampsia during pregnancy – summary – FAS_MOTHER analysis set

	Insulin detemir N=764	Other basal insulin N=828	No basal insulin N=781	Total N=2373
No	686 (93.3)	716 (89.9)	679 (88.9)	2081 (90.7)

GW: Gestational week, N: Number of patients, %: Percentage of patients, SD: Standard deviation

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14.1.25 HbA1c, hypoglycaemia, and pre-eclampsia during pregnancy – summary – MOTHER analysis set

	Insulin detemir N=727	Other basal insulin N=730	Total N=1457
HbA1c (%) at enrolment			
N	690	689	1379
Mean (SD)	6.95 (1.26)	7.15 (1.39)	7.05 (1.33)
Median	6.71	6.82	6.80
2.5; 97.5 percentiles	5.20; 10.29	5.35; 10.50	5.20; 10.39
Min; Max	4.40; 13.90	4.71; 14.50	4.40; 14.50
HbA1c (%) at conception (GW=2)			
N	261	249	510
Mean (SD)	7.13 (1.35)	7.31 (1.44)	7.22 (1.39)
Median	6.90	7.00	6.91
2.5; 97.5 percentiles	5.35; 10.66	5.44; 11.03	5.40; 10.90
Min; Max	4.99; 13.90	4.80; 14.05	4.80; 14.05
HbA1c (%) at end of first trimester (GW=12)			
N	672	688	1360
Mean (SD)	6.54 (1.09)	6.72 (1.20)	6.63 (1.15)
Median	6.36	6.50	6.40
2.5; 97.5 percentiles	4.90; 9.00	5.10; 9.93	5.00; 9.44
Min; Max	4.40; 11.90	4.60; 14.50	4.40; 14.50
HbA1c (%) at end of second trimester (GW=28)			
N	648	644	1292
Mean (SD)	6.10 (0.82)	6.22 (0.89)	6.16 (0.86)
Median	5.99	6.08	6.00
2.5; 97.5 percentiles	4.80; 7.91	4.90; 8.37	4.80; 8.19
Min; Max	4.10; 10.66	3.98; 9.93	3.98; 10.66
HbA1c (%) at end of third trimester (GW=40)			
N	351	421	772
Mean (SD)	6.28 (0.83)	6.21 (0.75)	6.24 (0.79)
Median	6.27	6.10	6.18
2.5; 97.5 percentiles	5.00; 8.40	5.08; 7.70	5.00; 8.10
Min; Max	4.20; 11.85	4.60; 11.12	4.20; 11.85
HbA1c (%) at delivery			
N	712	704	1416
Mean (SD)	6.30 (0.98)	6.41 (0.98)	6.36 (0.98)
Median	6.19	6.27	6.20
2.5; 97.5 percentiles	4.90; 8.70	5.00; 8.74	4.90; 8.70
Min; Max	4.10; 11.85	3.98; 11.21	3.98; 11.85
Major hypoglycaemia during pregnancy, N (%)			
N	697	697	1394
Yes	42 (6.0)	63 (9.0)	105 (7.5)
No	655 (94.0)	634 (91.0)	1289 (92.5)
Pre-eclampsia during pregnancy, N (%)			
N	700	701	1401
Yes	45 (6.4)	70 (10.0)	115 (8.2)
No	655 (93.6)	631 (90.0)	1286 (91.8)

GW: Gestational week, N: Number of patients, %: Percentage of patients, SD: Standard deviation

14.1.26 Observed insulin dose during pregnancy - basal insulin treatment group at enrolment – summary – FAS_MOTHER

	Levemir/Insulin Detemir N=764	Other basal insulin N=828	No basal insulin N=781	Total N=2373
Basal insulin dose (units) Dose at enrolment				
N	757	824		1581
Mean (SD)	28.09 (19.11)	25.68 (17.38)		26.84 (18.26)
Median	24.00	22.00		23.00
2.5; 97.5 percentiles	7.00; 75.00	6.00; 70.00		6.00; 72.00
Min, Max	2.00; 200.00	2.00; 260.00		2.00; 260.00
Basal insulin dose (units/kg) Dose at enrolment				
N	729	791		1520
Mean (SD)	0.39 (0.22)	0.34 (0.19)		0.36 (0.21)
Median	0.36	0.31		0.33
2.5; 97.5 percentiles	0.10; 0.94	0.10; 0.75		0.10; 0.83
Min, Max	0.04; 2.11	0.04; 2.76		0.04; 2.76
Bolus insulin dose (units) Dose at enrolment				
N	720	774	702	2196
Mean (SD)	26.27 (16.30)	26.51 (18.15)	41.68 (20.60)	31.28 (19.74)
Median	24.00	23.00	39.60	26.80
2.5; 97.5 percentiles	6.75; 62.00	6.00; 72.00	13.00; 91.10	8.00; 80.20
Min, Max	1.00; 210.00	0.50; 180.00	1.00; 162.00	0.50; 210.00
Bolus insulin dose (units/kg) Dose at enrolment				
N	697	744	653	2094
Mean (SD)	0.37 (0.19)	0.35 (0.19)	0.57 (0.24)	0.43 (0.23)
Median	0.34	0.31	0.56	0.38
2.5; 97.5 percentiles	0.10; 0.81	0.10; 0.84	0.19; 1.12	0.12; 0.94

N: Number of patients, SD: Standard deviation

Observed insulin dose during pregnancy - basal insulin treatment group at enrolment – summary – FAS_MOTHER

	Levemir/Insulin Detemir N=764	Other basal insulin N=828	No basal insulin N=781	Total N=2373
Min, Max	0.01; 2.19	0.01; 1.54	0.02; 1.86	0.01; 2.19
Premix insulin dose (units) Dose at enrolment				
N	1	2	14	17
Mean (SD)	26.00	65.00 (57.98)	59.71 (50.07)	58.35 (48.17)
Median	26.00	65.00	46.00	44.00
2.5; 97.5 percentiles	26.00; 26.00	24.00; 106.00	6.00; 174.00	6.00; 174.00
Min, Max	26.00; 26.00	24.00; 106.00	6.00; 174.00	6.00; 174.00
Premix insulin dose (units/kg) Dose at enrolment				
N	1	2	14	17
Mean (SD)	0.48	0.61 (0.35)	0.60 (0.42)	0.59 (0.39)
Median	0.48	0.61	0.48	0.48
2.5; 97.5 percentiles	0.48; 0.48	0.36; 0.86	0.05; 1.51	0.05; 1.51
Min, Max	0.48; 0.48	0.36; 0.86	0.05; 1.51	0.05; 1.51
Total insulin dose (units) Dose at enrolment				
N	759	826	713	2298
Mean (SD)	52.98 (30.26)	50.62 (29.37)	42.21 (21.66)	48.79 (27.89)
Median	48.00	45.00	40.00	44.00
2.5; 97.5 percentiles	16.00; 123.00	12.50; 124.00	13.00; 95.28	13.50; 118.00
Min, Max	2.00; 410.00	3.00; 270.00	1.00; 174.00	1.00; 410.00
Total insulin dose (units/kg) Dose at enrolment				
N	731	793	664	2188
Mean (SD)	0.74 (0.34)	0.67 (0.31)	0.57 (0.25)	0.66 (0.31)

N: Number of patients, SD: Standard deviation

Observed insulin dose during pregnancy - basal insulin treatment group at enrolment – summary – FAS_MOTHER

	Levemir/Insulin Detemir N=764	Other basal insulin N=828	No basal insulin N=781	Total N=2373
Median	0.69	0.63	0.56	0.62
2.5; 97.5 percentiles	0.24; 1.39	0.22; 1.33	0.18; 1.16	0.20; 1.34
Min, Max	0.06; 4.28	0.04; 2.87	0.02; 1.86	0.02; 4.28

N: Number of patients, SD: Standard deviation

14.1.27 Observed insulin dose during pregnancy stratified by basal insulin treatment group at enrolment – summary – MOTHER

	Levemir/Insulin Detemir N=727	Other basal insulin N=730	Total N=1457
Basal insulin dose (units) Dose at enrolment			
N	722	726	1448
Mean (SD)	28.00 (19.20)	25.36 (17.33)	26.68 (18.33)
Median	24.00	22.00	23.00
2.5; 97.5 percentiles	7.00; 75.00	6.00; 70.00	6.00; 72.00
Min, Max	2.00; 200.00	2.00; 260.00	2.00; 260.00
Basal insulin dose (units/kg) Dose at enrolment			
N	698	702	1400
Mean (SD)	0.39 (0.22)	0.34 (0.19)	0.36 (0.21)
Median	0.36	0.31	0.33
2.5; 97.5 percentiles	0.10; 0.89	0.10; 0.74	0.10; 0.81
Min, Max	0.04; 2.11	0.04; 2.76	0.04; 2.76
Bolus insulin dose (units) Dose at enrolment			
N	687	685	1372
Mean (SD)	26.15 (16.07)	25.91 (16.84)	26.03 (16.45)
Median	24.00	22.00	23.00
2.5; 97.5 percentiles	7.00; 62.00	7.00; 68.00	7.00; 66.00
Min, Max	1.00; 210.00	0.50; 150.00	0.50; 210.00
Bolus insulin dose (units/kg) Dose at enrolment			
N	667	664	1331
Mean (SD)	0.37 (0.19)	0.35 (0.19)	0.36 (0.19)
Median	0.34	0.31	0.32
2.5; 97.5 percentiles	0.10; 0.81	0.11; 0.84	0.11; 0.81
Min, Max	0.01; 2.19	0.01; 1.54	0.01; 2.19
Total insulin dose (units) Dose at enrolment			
N	723	728	1451

N: Number of patients, SD: Standard deviation

Observed insulin dose during pregnancy stratified by basal insulin treatment group at enrolment - summary - MOTHER

	Levemir/Insulin Detemir N=727	Other basal insulin N=730	Total N=1457
Mean (SD)	52.81 (30.39)	49.67 (28.23)	51.23 (29.36)
Median	48.00	44.00	46.00
2.5; 97.5 percentiles	16.00; 122.00	12.50; 116.00	15.00; 121.00
Min, Max	2.00; 410.00	3.00; 270.00	2.00; 410.00
Total insulin dose (units/kg) Dose at enrolment			
N	699	704	1403
Mean (SD)	0.73 (0.33)	0.67 (0.30)	0.70 (0.32)
Median	0.68	0.63	0.66
2.5; 97.5 percentiles	0.24; 1.39	0.22; 1.33	0.23; 1.36
Min, Max	0.06; 4.28	0.04; 2.87	0.04; 4.28

N: Number of patients, SD: Standard deviation

14.1.28 Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Number of subjects	764	828	781	2373
Medication during Pregnancy				
At any time during pregnancy, N (%)				
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	3 (0.4)	6 (0.7)	3 (0.4)	12 (0.5)
ACE INHIBITORS AND DIURETICS		1 (0.1)		1 (0.0)
ACE INHIBITORS, PLAIN	3 (0.4)	5 (0.6)	2 (0.3)	10 (0.4)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
ALL OTHER THERAPEUTIC PRODUCTS		2 (0.2)	3 (0.4)	5 (0.2)
ANTIDOTES		1 (0.1)		1 (0.0)
DRUGS FOR TREATMENT OF HYPERKALEMIA AND HYPERPHOSPHATEMIA			1 (0.1)	1 (0.0)
MEDICAL GASES			1 (0.1)	1 (0.0)
OTHER THERAPEUTIC PRODUCTS		1 (0.1)	1 (0.1)	2 (0.1)
ANALGESICS	76 (9.9)	119 (14.4)	115 (14.7)	310 (13.1)
ANILIDES	62 (8.1)	104 (12.6)	93 (11.9)	259 (10.9)
MORPHINAN DERIVATIVES			1 (0.1)	1 (0.0)
NATURAL OPIUM ALKALOIDS	17 (2.2)	28 (3.4)	36 (4.6)	81 (3.4)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	11 (1.4)	13 (1.6)	16 (2.0)	40 (1.7)
OTHER ANALGESICS AND ANTIPYRETICS	3 (0.4)	8 (1.0)	14 (1.8)	25 (1.1)
OTHER OPIOIDS	4 (0.5)	4 (0.5)	6 (0.8)	14 (0.6)
PHENYLPIPERIDINE DERIVATIVES	3 (0.4)	6 (0.7)	1 (0.1)	10 (0.4)
PYRAZOLONES	5 (0.7)	6 (0.7)	4 (0.5)	15 (0.6)
SELECTIVE SEROTONIN (5HT1) AGONISTS		2 (0.2)	5 (0.6)	7 (0.3)
Not coded	3 (0.4)	3 (0.4)	1 (0.1)	7 (0.3)
ANESTHETICS	21 (2.7)	33 (4.0)	54 (6.9)	108 (4.6)
AMIDES	6 (0.8)	20 (2.4)	38 (4.9)	64 (2.7)
OPIOID ANESTHETICS	2 (0.3)		1 (0.1)	3 (0.1)
OTHER GENERAL ANESTHETICS	7 (0.9)	7 (0.8)	8 (1.0)	22 (0.9)
Not coded	9 (1.2)	10 (1.2)	11 (1.4)	30 (1.3)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
ANTHELMINTICS		1 (0.1)		1 (0.0)
BENZIMIDAZOLE DERIVATIVES		1 (0.1)		1 (0.0)
ANTI-ACNE PREPARATIONS		1 (0.1)	2 (0.3)	3 (0.1)
ANTIINFECTIVES FOR TREATMENT OF ACNE		1 (0.1)		1 (0.0)
OTHER ANTI-ACNE PREPARATIONS FOR TOPICAL USE			1 (0.1)	1 (0.0)
RETINOIDS FOR TOPICAL USE IN ACNE			1 (0.1)	1 (0.0)
ANTI-PARKINSON DRUGS			1 (0.1)	1 (0.0)
MONOAMINE OXIDASE B INHIBITORS			1 (0.1)	1 (0.0)
ANTIANEMIC PREPARATIONS	65 (8.5)	122 (14.7)	137 (17.5)	324 (13.7)
FOLIC ACID AND DERIVATIVES	3 (0.4)	10 (1.2)	3 (0.4)	16 (0.7)
IRON BIVALENT, ORAL PREPARATIONS	37 (4.8)	61 (7.4)	77 (9.9)	175 (7.4)
IRON IN COMBINATION WITH FOLIC ACID	8 (1.0)	5 (0.6)	28 (3.6)	41 (1.7)
IRON IN OTHER COMBINATIONS	3 (0.4)	10 (1.2)	3 (0.4)	16 (0.7)
IRON TRIVALENT, ORAL PREPARATIONS		4 (0.5)	6 (0.8)	10 (0.4)
IRON, PARENTERAL PREPARATIONS	2 (0.3)	3 (0.4)	4 (0.5)	9 (0.4)
OTHER ANTIANEMIC PREPARATIONS		1 (0.1)	2 (0.3)	3 (0.1)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	14 (1.8)	45 (5.4)	27 (3.5)	86 (3.6)
Not coded		4 (0.5)	2 (0.3)	6 (0.3)
ANTIBACTERIALS FOR SYSTEMIC USE	68 (8.9)	107 (12.9)	90 (11.5)	265 (11.2)
BETA-LACTAMASE INHIBITORS		1 (0.1)		1 (0.0)
BETA-LACTAMASE RESISTANT PENICILLINS	3 (0.4)	4 (0.5)		7 (0.3)
BETA-LACTAMASE SENSITIVE PENICILLINS	2 (0.3)	9 (1.1)	3 (0.4)	14 (0.6)
CARBAPENEMS		2 (0.2)		2 (0.1)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	25 (3.3)	29 (3.5)	18 (2.3)	72 (3.0)
FIRST-GENERATION CEPHALOSPORINS	15 (2.0)	28 (3.4)	42 (5.4)	85 (3.6)
GLYCOPEPTIDE ANTIBACTERIALS		1 (0.1)		1 (0.0)
MACROLIDES	1 (0.1)			1 (0.0)
MONOBACTAMS		1 (0.1)		1 (0.0)
NITROFURAN DERIVATIVES	5 (0.7)	12 (1.4)	8 (1.0)	25 (1.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
OTHER ANTIBACTERIALS	4 (0.5)	10 (1.2)	3 (0.4)	17 (0.7)
PENICILLINS WITH EXTENDED SPECTRUM	22 (2.9)	30 (3.6)	26 (3.3)	78 (3.3)
SECOND-GENERATION CEPHALOSPORINS	2 (0.3)	1 (0.1)	3 (0.4)	6 (0.3)
THIRD-GENERATION CEPHALOSPORINS	4 (0.5)	3 (0.4)	4 (0.5)	11 (0.5)
TRIMETHOPRIM AND DERIVATIVES	3 (0.4)	3 (0.4)		6 (0.3)
Not coded		1 (0.1)	1 (0.1)	2 (0.1)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE		1 (0.1)		1 (0.0)
ANTIVIRALS		1 (0.1)		1 (0.0)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	1 (0.1)	1 (0.1)	7 (0.9)	9 (0.4)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (0.1)	1 (0.1)	6 (0.8)	8 (0.3)
ANTIDIARRHEAL MICROORGANISMS			1 (0.1)	1 (0.0)
ANTIEMETICS AND ANTINAUSEANTS	30 (3.9)	50 (6.0)	41 (5.2)	121 (5.1)
OTHER ANTIEMETICS	3 (0.4)	7 (0.8)	4 (0.5)	14 (0.6)
SEROTONIN (5HT3) ANTAGONISTS	28 (3.7)	44 (5.3)	37 (4.7)	109 (4.6)
ANTIEPILEPTICS	7 (0.9)	4 (0.5)	2 (0.3)	13 (0.5)
FATTY ACID DERIVATIVES	4 (0.5)	2 (0.2)		6 (0.3)
OTHER ANTIEPILEPTICS	3 (0.4)	3 (0.4)	2 (0.3)	8 (0.3)
ANTIFUNGALS FOR DERMATOLOGICAL USE		1 (0.1)		1 (0.0)
OTHER ANTIFUNGALS FOR TOPICAL USE		1 (0.1)		1 (0.0)
ANTIHEMORRHAGICS		1 (0.1)	2 (0.3)	3 (0.1)
FIBRINOGEN			2 (0.3)	2 (0.1)
VITAMIN K		1 (0.1)		1 (0.0)
ANTIHISTAMINES FOR SYSTEMIC USE	7 (0.9)	9 (1.1)	9 (1.2)	25 (1.1)
AMINOALKYL ETHERS		1 (0.1)		1 (0.0)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	3 (0.4)	2 (0.2)	3 (0.4)	8 (0.3)
PHENOTHIAZINE DERIVATIVES			3 (0.4)	3 (0.1)
PIPERAZINE DERIVATIVES	2 (0.3)	1 (0.1)		3 (0.1)
SUBSTITUTED ALKYLAMINES	2 (0.3)	5 (0.6)	3 (0.4)	10 (0.4)
ANTIHYPERTENSIVES	45 (5.9)	81 (9.8)	69 (8.8)	195 (8.2)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
ALPHA-ADRENORECEPTOR ANTAGONISTS		1 (0.1)	3 (0.4)	4 (0.2)
HYDRAZINOPHTHALAZINE DERIVATIVES	1 (0.1)	4 (0.5)	5 (0.6)	10 (0.4)
METHYLDOPA	44 (5.8)	79 (9.5)	62 (7.9)	185 (7.8)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	2 (0.3)		2 (0.3)	4 (0.2)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	1 (0.1)		1 (0.1)	2 (0.1)
FENAMATES	1 (0.1)		1 (0.1)	2 (0.1)
ANTIMYCOBACTERIALS		1 (0.1)		1 (0.0)
ANTIBIOTICS		1 (0.1)		1 (0.0)
OTHER DRUGS FOR TREATMENT OF TUBERCULOSIS		1 (0.1)		1 (0.0)
THIOCARBAMIDE DERIVATIVES		1 (0.1)		1 (0.0)
ANTIMYCOTICS FOR SYSTEMIC USE		1 (0.1)		1 (0.0)
TRIAZOLE DERIVATIVES		1 (0.1)		1 (0.0)
ANTINEOPLASTIC AGENTS		1 (0.1)		1 (0.0)
PURINE ANALOGUES		1 (0.1)		1 (0.0)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.		1 (0.1)		1 (0.0)
OTHER ANTIPRURITICS		1 (0.1)		1 (0.0)
ANTIPSORIATICS			1 (0.1)	1 (0.0)
OTHER ANTIPSORIATICS FOR TOPICAL USE			1 (0.1)	1 (0.0)
ANTISEPTICS AND DISINFECTANTS	1 (0.1)			1 (0.0)
OTHER ANTISEPTICS AND DISINFECTANTS	1 (0.1)			1 (0.0)
ANTITHROMBOTIC AGENTS	46 (6.0)	54 (6.5)	71 (9.1)	171 (7.2)
HEPARIN GROUP	46 (6.0)	54 (6.5)	71 (9.1)	171 (7.2)
ANTIVIRALS FOR SYSTEMIC USE	2 (0.3)	5 (0.6)	4 (0.5)	11 (0.5)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
NEURAMINIDASE INHIBITORS		4 (0.5)	3 (0.4)	7 (0.3)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	1 (0.1)			1 (0.0)
OTHER ANTIVIRALS		1 (0.1)		1 (0.0)
BETA BLOCKING AGENTS	44 (5.8)	82 (9.9)	51 (6.5)	177 (7.5)
ALPHA AND BETA BLOCKING AGENTS	38 (5.0)	75 (9.1)	50 (6.4)	163 (6.9)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
BETA BLOCKING AGENTS, NON-SELECTIVE	1 (0.1)		1 (0.1)	2 (0.1)
BETA BLOCKING AGENTS, SELECTIVE	5 (0.7)	7 (0.8)	1 (0.1)	13 (0.5)
BILE AND LIVER THERAPY	3 (0.4)	12 (1.4)	4 (0.5)	19 (0.8)
BILE ACIDS AND DERIVATIVES	3 (0.4)	11 (1.3)	4 (0.5)	18 (0.8)
LIVER THERAPY		1 (0.1)		1 (0.0)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	20 (2.6)	44 (5.3)	59 (7.6)	123 (5.2)
BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS		1 (0.1)	3 (0.4)	4 (0.2)
ELECTROLYTE SOLUTIONS		1 (0.1)	1 (0.1)	2 (0.1)
HYPERTONIC SOLUTIONS	1 (0.1)	2 (0.2)	4 (0.5)	7 (0.3)
OTHER BLOOD PRODUCTS	1 (0.1)		1 (0.1)	2 (0.1)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	11 (1.4)	33 (4.0)	44 (5.6)	88 (3.7)
SOLUTIONS FOR PARENTERAL NUTRITION	7 (0.9)	26 (3.1)	40 (5.1)	73 (3.1)
Not coded	2 (0.3)	1 (0.1)		3 (0.1)
CALCIUM CHANNEL BLOCKERS	4 (0.5)	5 (0.6)	14 (1.8)	23 (1.0)
DIHYDROPYRIDINE DERIVATIVES	4 (0.5)	5 (0.6)	14 (1.8)	23 (1.0)
CARDIAC THERAPY			2 (0.3)	2 (0.1)
OTHER CARDIAC PREPARATIONS			2 (0.3)	2 (0.1)
CORTICOSTEROIDS FOR SYSTEMIC USE			1 (0.1)	1 (0.0)
Not coded			1 (0.1)	1 (0.0)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1)	3 (0.4)	2 (0.3)	6 (0.3)
CORTICOSTEROIDS, POTENT (GROUP III)		1 (0.1)	2 (0.3)	3 (0.1)
CORTICOSTEROIDS, POTENT, COMBINATIONS WITH ANTIBIOTICS		1 (0.1)		1 (0.0)
CORTICOSTEROIDS, POTENT, OTHER COMBINATIONS	1 (0.1)			1 (0.0)
Not coded		1 (0.1)		1 (0.0)
COUGH AND COLD PREPARATIONS		2 (0.2)		2 (0.1)
EXPECTORANTS		1 (0.1)		1 (0.0)
OPIUM ALKALOIDS AND DERIVATIVES		1 (0.1)		1 (0.0)
DIURETICS	3 (0.4)	6 (0.7)	5 (0.6)	14 (0.6)
SULFONAMIDES, PLAIN	3 (0.4)	4 (0.5)	5 (0.6)	12 (0.5)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
THIAZIDES, PLAIN		2 (0.2)		2 (0.1)
DRUGS FOR ACID RELATED DISORDERS	40 (5.2)	77 (9.3)	71 (9.1)	188 (7.9)
ANTACIDS, OTHER COMBINATIONS	1 (0.1)		1 (0.1)	2 (0.1)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS		3 (0.4)	4 (0.5)	7 (0.3)
H2-RECEPTOR ANTAGONISTS	30 (3.9)	46 (5.6)	35 (4.5)	111 (4.7)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	2 (0.3)	5 (0.6)	1 (0.1)	8 (0.3)
PROTON PUMP INHIBITORS	14 (1.8)	29 (3.5)	36 (4.6)	79 (3.3)
Not coded		4 (0.5)	7 (0.9)	11 (0.5)
DRUGS FOR CONSTIPATION	5 (0.7)	10 (1.2)	6 (0.8)	21 (0.9)
CONTACT LAXATIVES	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
OSMOTICALLY ACTING LAXATIVES	4 (0.5)	8 (1.0)	5 (0.6)	17 (0.7)
OTHER DRUGS FOR CONSTIPATION		1 (0.1)		1 (0.0)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	17 (2.2)	34 (4.1)	66 (8.5)	117 (4.9)
BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AMMONIUM COMPOUNDS		2 (0.2)	4 (0.5)	6 (0.3)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	3 (0.4)	13 (1.6)	31 (4.0)	47 (2.0)
PAPAVERINE AND DERIVATIVES	2 (0.3)	3 (0.4)	15 (1.9)	20 (0.8)
PROPULSIVES	13 (1.7)	18 (2.2)	25 (3.2)	56 (2.4)
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP			1 (0.1)	1 (0.0)
SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM COMPOUNDS			1 (0.1)	1 (0.0)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	2 (0.3)	10 (1.2)	8 (1.0)	20 (0.8)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	1 (0.1)	7 (0.8)	7 (0.9)	15 (0.6)
LEUKOTRIENE RECEPTOR ANTAGONISTS	1 (0.1)	1 (0.1)		2 (0.1)
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES		1 (0.1)	1 (0.1)	2 (0.1)
XANTHINES		1 (0.1)		1 (0.0)
DRUGS FOR TREATMENT OF BONE DISEASES		1 (0.1)	1 (0.1)	2 (0.1)
BISPHOSPHONATES		1 (0.1)		1 (0.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION			1 (0.1)	1 (0.0)
DRUGS USED IN DIABETES	764 (100)	828 (100)	781 (100)	2373 (100)
BIGUANIDES	47 (6.2)	44 (5.3)	15 (1.9)	106 (4.5)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	1 (0.1)			1 (0.0)
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES		1 (0.1)	3 (0.4)	4 (0.2)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	757 (99.1)	814 (98.3)	770 (98.6)	2341 (98.7)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	1 (0.1)	6 (0.7)	15 (1.9)	22 (0.9)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	4 (0.5)	119 (14.4)	3 (0.4)	126 (5.3)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	764 (100)	720 (87.0)	10 (1.3)	1494 (63.0)
Not coded	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS			1 (0.1)	1 (0.0)
PYRETHRINES, INCL. SYNTHETIC COMPOUNDS			1 (0.1)	1 (0.0)
EMOLLIENTS AND PROTECTIVES		2 (0.2)	2 (0.3)	4 (0.2)
OTHER EMOLLIENTS AND PROTECTIVES		2 (0.2)	1 (0.1)	3 (0.1)
ZINC PRODUCTS			1 (0.1)	1 (0.0)
GENERAL NUTRIENTS	1 (0.1)	2 (0.2)	2 (0.3)	5 (0.2)
AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES			2 (0.3)	2 (0.1)
OTHER COMBINATIONS OF NUTRIENTS	1 (0.1)	1 (0.1)		2 (0.1)
Not coded		1 (0.1)		1 (0.0)
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	1 (0.1)	1 (0.1)	3 (0.4)	5 (0.2)
IMIDAZOLE DERIVATIVES		1 (0.1)	3 (0.4)	4 (0.2)
OTHER ANTIINFECTIVES AND ANTISEPTICS	1 (0.1)			1 (0.0)
IMMUNE SERA AND IMMUNOGLOBULINS	8 (1.0)	13 (1.6)	19 (2.4)	40 (1.7)
IMMUNOGLOBULINS, NORMAL HUMAN	1 (0.1)	1 (0.1)	3 (0.4)	5 (0.2)
SPECIFIC IMMUNOGLOBULINS	7 (0.9)	12 (1.4)	16 (2.0)	35 (1.5)
IMMUNOSUPPRESSANTS	1 (0.1)	3 (0.4)	2 (0.3)	6 (0.3)
OTHER IMMUNOSUPPRESSANTS		3 (0.4)	2 (0.3)	5 (0.2)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	1 (0.1)			1 (0.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
LIPID MODIFYING AGENTS	1 (0.1)	5 (0.6)	8 (1.0)	14 (0.6)
HMG COA REDUCTASE INHIBITORS	1 (0.1)	4 (0.5)	7 (0.9)	12 (0.5)
OTHER LIPID MODIFYING AGENTS		1 (0.1)	1 (0.1)	2 (0.1)
MINERAL SUPPLEMENTS	19 (2.5)	56 (6.8)	55 (7.0)	130 (5.5)
CALCIUM	13 (1.7)	29 (3.5)	20 (2.6)	62 (2.6)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	1 (0.1)	11 (1.3)	7 (0.9)	19 (0.8)
MAGNESIUM	5 (0.7)	17 (2.1)	30 (3.8)	52 (2.2)
OTHER MINERAL PRODUCTS			1 (0.1)	1 (0.0)
SELENIUM			2 (0.3)	2 (0.1)
SODIUM		1 (0.1)		1 (0.0)
MULTIPLE ATC, 0	540 (70.7)	715 (86.4)	695 (89.0)	1950 (82.2)
MULTIPLE ATC, 0	540 (70.7)	715 (86.4)	695 (89.0)	1950 (82.2)
MUSCLE RELAXANTS	1 (0.1)		3 (0.4)	4 (0.2)
CHOLINE DERIVATIVES	1 (0.1)		2 (0.3)	3 (0.1)
OTHER QUATERNARY AMMONIUM COMPOUNDS			2 (0.3)	2 (0.1)
NASAL PREPARATIONS		1 (0.1)		1 (0.0)
Not coded		1 (0.1)		1 (0.0)
OPHTHALMOLOGICALS	3 (0.4)	6 (0.7)	19 (2.4)	28 (1.2)
BETA BLOCKING AGENTS		1 (0.1)	3 (0.4)	4 (0.2)
OTHER ANTIINFECTIVES			1 (0.1)	1 (0.0)
OTHER OPHTHALMOLOGICALS	1 (0.1)	4 (0.5)	15 (1.9)	20 (0.8)
PARASYMPATHOMIMETICS			1 (0.1)	1 (0.0)
PROSTAGLANDIN ANALOGUES	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)			1 (0.0)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)			1 (0.0)
OTHER DERMATOLOGICAL PREPARATIONS		1 (0.1)	1 (0.1)	2 (0.1)
OTHER DERMATOLOGICALS		1 (0.1)	1 (0.1)	2 (0.1)
OTHER GYNECOLOGICALS	25 (3.3)	37 (4.5)	47 (6.0)	109 (4.6)
ERGOT ALKALOIDS			1 (0.1)	1 (0.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
ERGOT ALKALOIDS AND OXYTOCIN INCL. ANALOGUES, IN COMBINATION	4 (0.5)	4 (0.5)	1 (0.1)	9 (0.4)
OTHER GYNECOLOGICALS	8 (1.0)	8 (1.0)	4 (0.5)	20 (0.8)
PROSTAGLANDINS	14 (1.8)	27 (3.3)	41 (5.2)	82 (3.5)
SYMPATHOMIMETICS, LABOUR REPRESSANTS			1 (0.1)	1 (0.0)
OTHER NERVOUS SYSTEM DRUGS		6 (0.7)	2 (0.3)	8 (0.3)
ANTIVERTIGO PREPARATIONS		1 (0.1)		1 (0.0)
DRUGS USED IN NICOTINE DEPENDENCE		5 (0.6)	2 (0.3)	7 (0.3)
OTOLOGICALS		1 (0.1)		1 (0.0)
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION		1 (0.1)		1 (0.0)
PANCREATIC HORMONES	2 (0.3)	5 (0.6)	7 (0.9)	14 (0.6)
GLYCOGENOLYTIC HORMONES	2 (0.3)	5 (0.6)	7 (0.9)	14 (0.6)
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES	31 (4.1)	45 (5.4)	74 (9.5)	150 (6.3)
ACTH		1 (0.1)		1 (0.0)
OXYTOCIN AND ANALOGUES	31 (4.1)	44 (5.3)	74 (9.5)	149 (6.3)
PSYCHOANALEPTICS	9 (1.2)	15 (1.8)	10 (1.3)	34 (1.4)
CENTRALLY ACTING SYMPATHOMIMETICS	1 (0.1)	2 (0.2)	5 (0.6)	8 (0.3)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS		1 (0.1)	1 (0.1)	2 (0.1)
OTHER ANTIDEPRESSANTS		2 (0.2)		2 (0.1)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	8 (1.0)	10 (1.2)	6 (0.8)	24 (1.0)
PSYCHOLEPTICS	8 (1.0)	6 (0.7)	7 (0.9)	21 (0.9)
BENZODIAZEPINE DERIVATIVES	7 (0.9)	2 (0.2)	2 (0.3)	11 (0.5)
BENZODIAZEPINE RELATED DRUGS	1 (0.1)	2 (0.2)	2 (0.3)	5 (0.2)
MELATONIN RECEPTOR AGONISTS			2 (0.3)	2 (0.1)
OTHER ANTIPSYCHOTICS		1 (0.1)		1 (0.0)
PHENOTHIAZINES WITH ALIPHATIC SIDE-CHAIN		1 (0.1)	1 (0.1)	2 (0.1)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	10 (1.3)	11 (1.3)	17 (2.2)	38 (1.6)
GONADOTROPINS	1 (0.1)			1 (0.0)
OVULATION STIMULANTS, SYNTHETIC	1 (0.1)	1 (0.1)		2 (0.1)
PREGNADIEN DERIVATIVES	6 (0.8)	5 (0.6)	15 (1.9)	26 (1.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

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PREGNEN (4) DERIVATIVES	1 (0.1)			1 (0.0)
PROGESTERONE RECEPTOR MODULATORS	2 (0.3)	3 (0.4)	2 (0.3)	7 (0.3)
PROGESTOGENS AND ESTROGENS, SEQUENTIAL PREPARATIONS		2 (0.2)		2 (0.1)
STOMATOLOGICAL PREPARATIONS		1 (0.1)		1 (0.0)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT		1 (0.1)		1 (0.0)
THROAT PREPARATIONS		1 (0.1)		1 (0.0)
ANTISEPTICS		1 (0.1)		1 (0.0)
THYROID THERAPY	169 (22.1)	224 (27.1)	247 (31.6)	640 (27.0)
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	2 (0.3)	1 (0.1)	3 (0.4)	6 (0.3)
THIOURACILS	4 (0.5)	2 (0.2)	10 (1.3)	16 (0.7)
THYROID HORMONES	163 (21.3)	221 (26.7)	235 (30.1)	619 (26.1)
TONICS	3 (0.4)	10 (1.2)	3 (0.4)	16 (0.7)
Not coded	3 (0.4)	10 (1.2)	3 (0.4)	16 (0.7)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE		2 (0.2)	3 (0.4)	5 (0.2)
Not coded		2 (0.2)	3 (0.4)	5 (0.2)
UROLOGICALS	1 (0.1)			1 (0.0)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	1 (0.1)			1 (0.0)
VACCINES	6 (0.8)	15 (1.8)	16 (2.0)	37 (1.6)
BACTERIAL AND VIRAL VACCINES, COMBINED	2 (0.3)	3 (0.4)	1 (0.1)	6 (0.3)
INFLUENZA VACCINES	4 (0.5)	12 (1.4)	14 (1.8)	30 (1.3)
PERTUSSIS VACCINES	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
TETANUS VACCINES		1 (0.1)		1 (0.0)
VASOPROTECTIVES	2 (0.3)	1 (0.1)	5 (0.6)	8 (0.3)
BIOFLAVONOIDS	1 (0.1)	1 (0.1)		2 (0.1)
LOCAL ANESTHETICS	1 (0.1)		3 (0.4)	4 (0.2)
OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS ANDANAL FISSURES FOR TOPICAL USE	1 (0.1)		4 (0.5)	5 (0.2)
VITAMINS	89 (11.6)	173 (20.9)	178 (22.8)	440 (18.5)
COMBINATIONS OF VITAMINS			1 (0.1)	1 (0.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
MULTIVITAMINS WITH MINERALS	18 (2.4)	35 (4.2)	15 (1.9)	68 (2.9)
MULTIVITAMINS, OTHER COMBINATIONS	5 (0.7)	18 (2.2)	15 (1.9)	38 (1.6)
VITAMIN B-COMPLEX WITH VITAMIN C	2 (0.3)	1 (0.1)		3 (0.1)
VITAMIN B-COMPLEX, OTHER COMBINATIONS	2 (0.3)	2 (0.2)	10 (1.3)	14 (0.6)
VITAMIN B-COMPLEX, PLAIN	2 (0.3)	12 (1.4)	1 (0.1)	15 (0.6)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12		1 (0.1)		1 (0.0)
VITAMIN B1, PLAIN	2 (0.3)	3 (0.4)	1 (0.1)	6 (0.3)
VITAMIN D AND ANALOGUES	43 (5.6)	85 (10.3)	110 (14.1)	238 (10.0)
VITAMINS WITH MINERALS	7 (0.9)	15 (1.8)	16 (2.0)	38 (1.6)
VITAMINS, OTHER COMBINATIONS	10 (1.3)	13 (1.6)	26 (3.3)	49 (2.1)
Not coded	2 (0.3)	6 (0.7)	5 (0.6)	13 (0.5)
During first trimester, N (%)				
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	3 (0.4)	4 (0.5)	3 (0.4)	10 (0.4)
ACE INHIBITORS AND DIURETICS		1 (0.1)		1 (0.0)
ACE INHIBITORS, PLAIN	3 (0.4)	3 (0.4)	2 (0.3)	8 (0.3)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
ANALGESICS	9 (1.2)	19 (2.3)	7 (0.9)	35 (1.5)
ANILIDES	6 (0.8)	18 (2.2)	4 (0.5)	28 (1.2)
NATURAL OPIUM ALKALOIDS		2 (0.2)		2 (0.1)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS		1 (0.1)	2 (0.3)	3 (0.1)
OTHER OPIOIDS	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
PHENYLPIPERIDINE DERIVATIVES	1 (0.1)			1 (0.0)
PYRAZOLONES	1 (0.1)	1 (0.1)		2 (0.1)
SELECTIVE SEROTONIN (5HT1) AGONISTS			2 (0.3)	2 (0.1)
ANESTHETICS			1 (0.1)	1 (0.0)
OTHER GENERAL ANESTHETICS			1 (0.1)	1 (0.0)
ANTHELMINTICS		1 (0.1)		1 (0.0)
BENZIMIDAZOLE DERIVATIVES		1 (0.1)		1 (0.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
ANTI-ACNE PREPARATIONS		1 (0.1)	2 (0.3)	3 (0.1)
ANTIINFECTIVES FOR TREATMENT OF ACNE		1 (0.1)		1 (0.0)
OTHER ANTI-ACNE PREPARATIONS FOR TOPICAL USE			1 (0.1)	1 (0.0)
RETINOIDS FOR TOPICAL USE IN ACNE			1 (0.1)	1 (0.0)
ANTIANEMIC PREPARATIONS	38 (5.0)	76 (9.2)	68 (8.7)	182 (7.7)
FOLIC ACID AND DERIVATIVES	3 (0.4)	9 (1.1)	2 (0.3)	14 (0.6)
IRON BIVALENT, ORAL PREPARATIONS	13 (1.7)	18 (2.2)	23 (2.9)	54 (2.3)
IRON IN COMBINATION WITH FOLIC ACID	5 (0.7)	2 (0.2)	15 (1.9)	22 (0.9)
IRON IN OTHER COMBINATIONS	3 (0.4)	5 (0.6)	1 (0.1)	9 (0.4)
IRON TRIVALENT, ORAL PREPARATIONS		3 (0.4)	1 (0.1)	4 (0.2)
IRON, PARENTERAL PREPARATIONS			1 (0.1)	1 (0.0)
OTHER ANTIANEMIC PREPARATIONS			2 (0.3)	2 (0.1)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	14 (1.8)	42 (5.1)	22 (2.8)	78 (3.3)
Not coded		4 (0.5)	2 (0.3)	6 (0.3)
ANTIBACTERIALS FOR SYSTEMIC USE	10 (1.3)	22 (2.7)	13 (1.7)	45 (1.9)
BETA-LACTAMASE RESISTANT PENICILLINS	1 (0.1)			1 (0.0)
BETA-LACTAMASE SENSITIVE PENICILLINS		3 (0.4)		3 (0.1)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS		4 (0.5)	1 (0.1)	5 (0.2)
FIRST-GENERATION CEPHALOSPORINS	3 (0.4)	2 (0.2)	3 (0.4)	8 (0.3)
MONOBACTAMS		1 (0.1)		1 (0.0)
NITROFURAN DERIVATIVES	3 (0.4)	2 (0.2)		5 (0.2)
OTHER ANTIBACTERIALS	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
PENICILLINS WITH EXTENDED SPECTRUM	4 (0.5)	6 (0.7)	5 (0.6)	15 (0.6)
SECOND-GENERATION CEPHALOSPORINS			1 (0.1)	1 (0.0)
THIRD-GENERATION CEPHALOSPORINS	2 (0.3)	1 (0.1)	2 (0.3)	5 (0.2)
Not coded		1 (0.1)		1 (0.0)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE		1 (0.1)		1 (0.0)
ANTIVIRALS		1 (0.1)		1 (0.0)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	1 (0.1)	1 (0.1)	5 (0.6)	7 (0.3)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

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AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (0.1)	1 (0.1)	5 (0.6)	7 (0.3)
ANTIEMETICS AND ANTINAUSEANTS	6 (0.8)	14 (1.7)	7 (0.9)	27 (1.1)
OTHER ANTIEMETICS	3 (0.4)	7 (0.8)	2 (0.3)	12 (0.5)
SEROTONIN (5HT3) ANTAGONISTS	4 (0.5)	7 (0.8)	5 (0.6)	16 (0.7)
ANTIEPILEPTICS	7 (0.9)	4 (0.5)	2 (0.3)	13 (0.5)
FATTY ACID DERIVATIVES	4 (0.5)	2 (0.2)		6 (0.3)
OTHER ANTIEPILEPTICS	3 (0.4)	3 (0.4)	2 (0.3)	8 (0.3)
ANTIFUNGALS FOR DERMATOLOGICAL USE		1 (0.1)		1 (0.0)
OTHER ANTIFUNGALS FOR TOPICAL USE		1 (0.1)		1 (0.0)
ANTIHEMORRHAGICS		1 (0.1)		1 (0.0)
VITAMIN K		1 (0.1)		1 (0.0)
ANTIHISTAMINES FOR SYSTEMIC USE	4 (0.5)	4 (0.5)	4 (0.5)	12 (0.5)
AMINOALKYL ETHERS		1 (0.1)		1 (0.0)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	2 (0.3)	2 (0.2)	3 (0.4)	7 (0.3)
PHENOTHIAZINE DERIVATIVES			1 (0.1)	1 (0.0)
PIPERAZINE DERIVATIVES	2 (0.3)	1 (0.1)		3 (0.1)
ANTIHYPERTENSIVES	26 (3.4)	29 (3.5)	22 (2.8)	77 (3.2)
ALPHA-ADRENORECEPTOR ANTAGONISTS			1 (0.1)	1 (0.0)
METHYLDOPA	26 (3.4)	29 (3.5)	21 (2.7)	76 (3.2)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS			2 (0.3)	2 (0.1)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES			1 (0.1)	1 (0.0)
FENAMATES			1 (0.1)	1 (0.0)
ANTIMYCOBACTERIALS		1 (0.1)		1 (0.0)
ANTIBIOTICS		1 (0.1)		1 (0.0)
OTHER DRUGS FOR TREATMENT OF TUBERCULOSIS		1 (0.1)		1 (0.0)
THIOCARBAMIDE DERIVATIVES		1 (0.1)		1 (0.0)
ANTIMYCOTICS FOR SYSTEMIC USE		1 (0.1)		1 (0.0)
TRIAZOLE DERIVATIVES		1 (0.1)		1 (0.0)
ANTINEOPLASTIC AGENTS		1 (0.1)		1 (0.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

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PURINE ANALOGUES		1 (0.1)		1 (0.0)
ANTIPSORIATICS			1 (0.1)	1 (0.0)
OTHER ANTIPSORIATICS FOR TOPICAL USE			1 (0.1)	1 (0.0)
ANTITHROMBOTIC AGENTS	14 (1.8)	9 (1.1)	15 (1.9)	38 (1.6)
HEPARIN GROUP	14 (1.8)	9 (1.1)	15 (1.9)	38 (1.6)
ANTIVIRALS FOR SYSTEMIC USE	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS		1 (0.1)	1 (0.1)	2 (0.1)
NEURAMINIDASE INHIBITORS			1 (0.1)	1 (0.0)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	1 (0.1)			1 (0.0)
OTHER ANTIVIRALS		1 (0.1)		1 (0.0)
BETA BLOCKING AGENTS	14 (1.8)	19 (2.3)	13 (1.7)	46 (1.9)
ALPHA AND BETA BLOCKING AGENTS	9 (1.2)	15 (1.8)	13 (1.7)	37 (1.6)
BETA BLOCKING AGENTS, SELECTIVE	5 (0.7)	4 (0.5)		9 (0.4)
BILE AND LIVER THERAPY	1 (0.1)	3 (0.4)		4 (0.2)
BILE ACIDS AND DERIVATIVES	1 (0.1)	2 (0.2)		3 (0.1)
LIVER THERAPY		1 (0.1)		1 (0.0)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS		1 (0.1)	3 (0.4)	4 (0.2)
HYPERTONIC SOLUTIONS			1 (0.1)	1 (0.0)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE			2 (0.3)	2 (0.1)
SOLUTIONS FOR PARENTERAL NUTRITION		1 (0.1)		1 (0.0)
CALCIUM CHANNEL BLOCKERS	2 (0.3)	1 (0.1)	4 (0.5)	7 (0.3)
DIHYDROPYRIDINE DERIVATIVES	2 (0.3)	1 (0.1)	4 (0.5)	7 (0.3)
CORTICOSTEROIDS FOR SYSTEMIC USE			1 (0.1)	1 (0.0)
Not coded			1 (0.1)	1 (0.0)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1)	2 (0.2)	2 (0.3)	5 (0.2)
CORTICOSTEROIDS, POTENT (GROUP III)			2 (0.3)	2 (0.1)
CORTICOSTEROIDS, POTENT, COMBINATIONS WITH ANTIBIOTICS		1 (0.1)		1 (0.0)
CORTICOSTEROIDS, POTENT, OTHER COMBINATIONS	1 (0.1)			1 (0.0)
Not coded		1 (0.1)		1 (0.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
DIURETICS	1 (0.1)	2 (0.2)	2 (0.3)	5 (0.2)
SULFONAMIDES, PLAIN	1 (0.1)	2 (0.2)	2 (0.3)	5 (0.2)
DRUGS FOR ACID RELATED DISORDERS	8 (1.0)	22 (2.7)	20 (2.6)	50 (2.1)
ANTACIDS, OTHER COMBINATIONS	1 (0.1)			1 (0.0)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS			1 (0.1)	1 (0.0)
H2-RECEPTOR ANTAGONISTS	3 (0.4)	4 (0.5)	1 (0.1)	8 (0.3)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)		2 (0.2)		2 (0.1)
PROTON PUMP INHIBITORS	5 (0.7)	17 (2.1)	18 (2.3)	40 (1.7)
Not coded		1 (0.1)		1 (0.0)
DRUGS FOR CONSTIPATION	3 (0.4)	5 (0.6)	5 (0.6)	13 (0.5)
CONTACT LAXATIVES	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
OSMOTICALLY ACTING LAXATIVES	2 (0.3)	4 (0.5)	4 (0.5)	10 (0.4)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	3 (0.4)	6 (0.7)	10 (1.3)	19 (0.8)
BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AMMONIUM COMPOUNDS		1 (0.1)		1 (0.0)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS		1 (0.1)	3 (0.4)	4 (0.2)
PAPAVERINE AND DERIVATIVES	1 (0.1)			1 (0.0)
PROPULSIVES	2 (0.3)	4 (0.5)	7 (0.9)	13 (0.5)
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP			1 (0.1)	1 (0.0)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	2 (0.3)	7 (0.8)	8 (1.0)	17 (0.7)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	1 (0.1)	5 (0.6)	7 (0.9)	13 (0.5)
LEUKOTRIENE RECEPTOR ANTAGONISTS	1 (0.1)	1 (0.1)		2 (0.1)
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES		1 (0.1)	1 (0.1)	2 (0.1)
DRUGS FOR TREATMENT OF BONE DISEASES		1 (0.1)		1 (0.0)
BISPHOSPHONATES		1 (0.1)		1 (0.0)
DRUGS USED IN DIABETES	764 (100)	827 (99.9)	781 (100)	2372 (100)
BIGUANIDES	44 (5.8)	36 (4.3)	11 (1.4)	91 (3.8)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	1 (0.1)			1 (0.0)
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES		1 (0.1)	3 (0.4)	4 (0.2)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	750 (98.2)	805 (97.2)	767 (98.2)	2322 (97.9)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	1 (0.1)	4 (0.5)	14 (1.8)	19 (0.8)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	2 (0.3)	116 (14.0)	3 (0.4)	121 (5.1)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	762 (99.7)	714 (86.2)	4 (0.5)	1480 (62.4)
Not coded	1 (0.1)			1 (0.0)
GENERAL NUTRIENTS	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES			1 (0.1)	1 (0.0)
OTHER COMBINATIONS OF NUTRIENTS	1 (0.1)	1 (0.1)		2 (0.1)
IMMUNE SERA AND IMMUNOGLOBULINS		2 (0.2)	1 (0.1)	3 (0.1)
IMMUNOGLOBULINS, NORMAL HUMAN		1 (0.1)	1 (0.1)	2 (0.1)
SPECIFIC IMMUNOGLOBULINS		1 (0.1)		1 (0.0)
IMMUNOSUPPRESSANTS	1 (0.1)	3 (0.4)	2 (0.3)	6 (0.3)
OTHER IMMUNOSUPPRESSANTS		3 (0.4)	2 (0.3)	5 (0.2)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	1 (0.1)			1 (0.0)
LIPID MODIFYING AGENTS	1 (0.1)	4 (0.5)	8 (1.0)	13 (0.5)
HMG COA REDUCTASE INHIBITORS	1 (0.1)	4 (0.5)	7 (0.9)	12 (0.5)
OTHER LIPID MODIFYING AGENTS			1 (0.1)	1 (0.0)
MINERAL SUPPLEMENTS	15 (2.0)	45 (5.4)	33 (4.2)	93 (3.9)
CALCIUM	13 (1.7)	28 (3.4)	20 (2.6)	61 (2.6)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	1 (0.1)	11 (1.3)	6 (0.8)	18 (0.8)
MAGNESIUM	1 (0.1)	7 (0.8)	9 (1.2)	17 (0.7)
SODIUM		1 (0.1)		1 (0.0)
MULTIPLE ATC, 0	524 (68.6)	688 (83.1)	674 (86.3)	1886 (79.5)
MULTIPLE ATC, 0	524 (68.6)	688 (83.1)	674 (86.3)	1886 (79.5)
OPHTHALMOLOGICALS	3 (0.4)	4 (0.5)	6 (0.8)	13 (0.5)
BETA BLOCKING AGENTS		1 (0.1)	3 (0.4)	4 (0.2)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
OTHER OPHTHALMOLOGICALS	1 (0.1)	2 (0.2)	3 (0.4)	6 (0.3)
PARASYMPATHOMIMETICS			1 (0.1)	1 (0.0)
PROSTAGLANDIN ANALOGUES	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)			1 (0.0)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)			1 (0.0)
OTHER GYNECOLOGICALS	2 (0.3)	1 (0.1)		3 (0.1)
OTHER GYNECOLOGICALS	1 (0.1)			1 (0.0)
PROSTAGLANDINS	1 (0.1)	1 (0.1)		2 (0.1)
OTHER NERVOUS SYSTEM DRUGS		3 (0.4)	1 (0.1)	4 (0.2)
ANTIVERTIGO PREPARATIONS		1 (0.1)		1 (0.0)
DRUGS USED IN NICOTINE DEPENDENCE		2 (0.2)	1 (0.1)	3 (0.1)
PANCREATIC HORMONES	2 (0.3)	1 (0.1)	4 (0.5)	7 (0.3)
GLYCOGENOLYTIC HORMONES	2 (0.3)	1 (0.1)	4 (0.5)	7 (0.3)
PSYCHOANALEPTICS	9 (1.2)	15 (1.8)	9 (1.2)	33 (1.4)
CENTRALLY ACTING SYMPATHOMIMETICS	1 (0.1)	2 (0.2)	5 (0.6)	8 (0.3)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS		1 (0.1)	1 (0.1)	2 (0.1)
OTHER ANTIDEPRESSANTS		2 (0.2)		2 (0.1)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	8 (1.0)	10 (1.2)	5 (0.6)	23 (1.0)
PSYCHOLEPTICS	2 (0.3)	3 (0.4)	4 (0.5)	9 (0.4)
BENZODIAZEPINE DERIVATIVES	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
MELATONIN RECEPTOR AGONISTS			2 (0.3)	2 (0.1)
OTHER ANTIPSYCHOTICS		1 (0.1)		1 (0.0)
PHENOTHIAZINES WITH ALIPHATIC SIDE-CHAIN		1 (0.1)	1 (0.1)	2 (0.1)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	7 (0.9)	6 (0.7)	10 (1.3)	23 (1.0)
GONADOTROPINS	1 (0.1)			1 (0.0)
OVULATION STIMULANTS, SYNTHETIC	1 (0.1)	1 (0.1)		2 (0.1)
PREGNADIEN DERIVATIVES	5 (0.7)	3 (0.4)	9 (1.2)	17 (0.7)
PROGESTERONE RECEPTOR MODULATORS	1 (0.1)		1 (0.1)	2 (0.1)
PROGESTOGENS AND ESTROGENS, SEQUENTIAL PREPARATIONS		2 (0.2)		2 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
THYROID THERAPY	157 (20.5)	200 (24.2)	230 (29.4)	587 (24.7)
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	2 (0.3)	1 (0.1)	2 (0.3)	5 (0.2)
THIOURACILS	4 (0.5)	2 (0.2)	10 (1.3)	16 (0.7)
THYROID HORMONES	151 (19.8)	197 (23.8)	219 (28.0)	567 (23.9)
TONICS	3 (0.4)	8 (1.0)	2 (0.3)	13 (0.5)
Not coded	3 (0.4)	8 (1.0)	2 (0.3)	13 (0.5)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE			3 (0.4)	3 (0.1)
Not coded			3 (0.4)	3 (0.1)
UROLOGICALS	1 (0.1)			1 (0.0)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	1 (0.1)			1 (0.0)
VACCINES		3 (0.4)	4 (0.5)	7 (0.3)
INFLUENZA VACCINES		3 (0.4)	4 (0.5)	7 (0.3)
VASOPROTECTIVES	1 (0.1)			1 (0.0)
BIOFLAVONOIDS	1 (0.1)			1 (0.0)
VITAMINS	78 (10.2)	137 (16.5)	151 (19.3)	366 (15.4)
COMBINATIONS OF VITAMINS			1 (0.1)	1 (0.0)
MULTIVITAMINS WITH MINERALS	18 (2.4)	29 (3.5)	13 (1.7)	60 (2.5)
MULTIVITAMINS, OTHER COMBINATIONS	5 (0.7)	17 (2.1)	12 (1.5)	34 (1.4)
VITAMIN B-COMPLEX WITH VITAMIN C	1 (0.1)	1 (0.1)		2 (0.1)
VITAMIN B-COMPLEX, OTHER COMBINATIONS	1 (0.1)	1 (0.1)	7 (0.9)	9 (0.4)
VITAMIN B-COMPLEX, PLAIN	1 (0.1)	12 (1.4)	1 (0.1)	14 (0.6)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12		1 (0.1)		1 (0.0)
VITAMIN B1, PLAIN		2 (0.2)		2 (0.1)
VITAMIN D AND ANALOGUES	40 (5.2)	65 (7.9)	90 (11.5)	195 (8.2)
VITAMINS WITH MINERALS	6 (0.8)	12 (1.4)	15 (1.9)	33 (1.4)
VITAMINS, OTHER COMBINATIONS	8 (1.0)	6 (0.7)	19 (2.4)	33 (1.4)
Not coded	2 (0.3)	6 (0.7)	5 (0.6)	13 (0.5)

During second trimester, N (%)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	3 (0.4)	2 (0.2)		5 (0.2)
ACE INHIBITORS AND DIURETICS		1 (0.1)		1 (0.0)
ACE INHIBITORS, PLAIN	3 (0.4)	1 (0.1)		4 (0.2)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	1 (0.1)			1 (0.0)
ANALGESICS	24 (3.1)	42 (5.1)	29 (3.7)	95 (4.0)
ANILIDES	21 (2.7)	34 (4.1)	20 (2.6)	75 (3.2)
NATURAL OPIUM ALKALOIDS	3 (0.4)	4 (0.5)	2 (0.3)	9 (0.4)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	2 (0.3)	6 (0.7)	5 (0.6)	13 (0.5)
OTHER ANALGESICS AND ANTIPYRETICS			1 (0.1)	1 (0.0)
OTHER OPIOIDS	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
PHENYLPIPERIDINE DERIVATIVES	1 (0.1)	3 (0.4)		4 (0.2)
PYRAZOLONES		2 (0.2)	1 (0.1)	3 (0.1)
SELECTIVE SEROTONIN (5HT1) AGONISTS		2 (0.2)	5 (0.6)	7 (0.3)
Not coded	1 (0.1)	2 (0.2)		3 (0.1)
ANESTHETICS	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
AMIDES	1 (0.1)	1 (0.1)		2 (0.1)
OPIOID ANESTHETICS	1 (0.1)			1 (0.0)
OTHER GENERAL ANESTHETICS	1 (0.1)		1 (0.1)	2 (0.1)
Not coded			1 (0.1)	1 (0.0)
ANTHELMINTICS		1 (0.1)		1 (0.0)
BENZIMIDAZOLE DERIVATIVES		1 (0.1)		1 (0.0)
ANTI-ACNE PREPARATIONS		1 (0.1)	1 (0.1)	2 (0.1)
ANTIINFECTIVES FOR TREATMENT OF ACNE		1 (0.1)		1 (0.0)
RETINOIDS FOR TOPICAL USE IN ACNE			1 (0.1)	1 (0.0)
ANTI-PARKINSON DRUGS			1 (0.1)	1 (0.0)
MONOAMINE OXIDASE B INHIBITORS			1 (0.1)	1 (0.0)
ANTIANEMIC PREPARATIONS	42 (5.5)	95 (11.5)	103 (13.2)	240 (10.1)
FOLIC ACID AND DERIVATIVES	2 (0.3)	10 (1.2)	2 (0.3)	14 (0.6)
IRON BIVALENT, ORAL PREPARATIONS	21 (2.7)	41 (5.0)	51 (6.5)	113 (4.8)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
IRON IN COMBINATION WITH FOLIC ACID	5 (0.7)	4 (0.5)	22 (2.8)	31 (1.3)
IRON IN OTHER COMBINATIONS	2 (0.3)	7 (0.8)	2 (0.3)	11 (0.5)
IRON TRIVALENT, ORAL PREPARATIONS		3 (0.4)	5 (0.6)	8 (0.3)
IRON, PARENTERAL PREPARATIONS	1 (0.1)		1 (0.1)	2 (0.1)
OTHER ANTIANEMIC PREPARATIONS		1 (0.1)	1 (0.1)	2 (0.1)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	13 (1.7)	40 (4.8)	23 (2.9)	76 (3.2)
Not coded		4 (0.5)	2 (0.3)	6 (0.3)
ANTIBACTERIALS FOR SYSTEMIC USE	32 (4.2)	50 (6.0)	21 (2.7)	103 (4.3)
BETA-LACTAMASE RESISTANT PENICILLINS	2 (0.3)	2 (0.2)		4 (0.2)
BETA-LACTAMASE SENSITIVE PENICILLINS		6 (0.7)	2 (0.3)	8 (0.3)
CARBAPENEMS		1 (0.1)		1 (0.0)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	6 (0.8)	10 (1.2)	6 (0.8)	22 (0.9)
FIRST-GENERATION CEPHALOSPORINS	3 (0.4)	6 (0.7)	3 (0.4)	12 (0.5)
MONOBACTAMS		1 (0.1)		1 (0.0)
NITROFURAN DERIVATIVES	5 (0.7)	8 (1.0)	4 (0.5)	17 (0.7)
OTHER ANTIBACTERIALS	2 (0.3)	7 (0.8)	1 (0.1)	10 (0.4)
PENICILLINS WITH EXTENDED SPECTRUM	16 (2.1)	15 (1.8)	8 (1.0)	39 (1.6)
SECOND-GENERATION CEPHALOSPORINS	2 (0.3)	1 (0.1)		3 (0.1)
THIRD-GENERATION CEPHALOSPORINS	3 (0.4)	2 (0.2)	2 (0.3)	7 (0.3)
TRIMETHOPRIM AND DERIVATIVES	1 (0.1)	1 (0.1)		2 (0.1)
Not coded		1 (0.1)		1 (0.0)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE		1 (0.1)		1 (0.0)
ANTIVIRALS		1 (0.1)		1 (0.0)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	1 (0.1)	1 (0.1)	5 (0.6)	7 (0.3)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (0.1)	1 (0.1)	5 (0.6)	7 (0.3)
ANTIEMETICS AND ANTINAUSEANTS	12 (1.6)	23 (2.8)	13 (1.7)	48 (2.0)
OTHER ANTIEMETICS	1 (0.1)	6 (0.7)	3 (0.4)	10 (0.4)
SEROTONIN (5HT3) ANTAGONISTS	11 (1.4)	17 (2.1)	10 (1.3)	38 (1.6)
ANTIEPILEPTICS	7 (0.9)	4 (0.5)	2 (0.3)	13 (0.5)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
FATTY ACID DERIVATIVES	4 (0.5)	2 (0.2)		6 (0.3)
OTHER ANTIEPILEPTICS	3 (0.4)	3 (0.4)	2 (0.3)	8 (0.3)
ANTIFUNGALS FOR DERMATOLOGICAL USE		1 (0.1)		1 (0.0)
OTHER ANTIFUNGALS FOR TOPICAL USE		1 (0.1)		1 (0.0)
ANTIHEMORRHAGICS		1 (0.1)		1 (0.0)
VITAMIN K		1 (0.1)		1 (0.0)
ANTIHISTAMINES FOR SYSTEMIC USE	4 (0.5)	7 (0.8)	4 (0.5)	15 (0.6)
AMINOALKYL ETHERS		1 (0.1)		1 (0.0)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	2 (0.3)	2 (0.2)	3 (0.4)	7 (0.3)
PIPERAZINE DERIVATIVES	2 (0.3)	1 (0.1)		3 (0.1)
SUBSTITUTED ALKYLAMINES		3 (0.4)	1 (0.1)	4 (0.2)
ANTIHYPERTENSIVES	25 (3.3)	38 (4.6)	32 (4.1)	95 (4.0)
ALPHA-ADRENORECEPTOR ANTAGONISTS			1 (0.1)	1 (0.0)
HYDRAZINOPHTHALAZINE DERIVATIVES			1 (0.1)	1 (0.0)
METHYLDOPA	25 (3.3)	38 (4.6)	31 (4.0)	94 (4.0)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	1 (0.1)		1 (0.1)	2 (0.1)
FENAMATES	1 (0.1)		1 (0.1)	2 (0.1)
ANTIMYCOBACTERIALS		1 (0.1)		1 (0.0)
ANTIBIOTICS		1 (0.1)		1 (0.0)
OTHER DRUGS FOR TREATMENT OF TUBERCULOSIS		1 (0.1)		1 (0.0)
THIOCARBAMIDE DERIVATIVES		1 (0.1)		1 (0.0)
ANTIMYCOTICS FOR SYSTEMIC USE		1 (0.1)		1 (0.0)
TRIAZOLE DERIVATIVES		1 (0.1)		1 (0.0)
ANTINEOPLASTIC AGENTS		1 (0.1)		1 (0.0)
PURINE ANALOGUES		1 (0.1)		1 (0.0)
ANTIPSORIATICS			1 (0.1)	1 (0.0)
OTHER ANTIPSORIATICS FOR TOPICAL USE			1 (0.1)	1 (0.0)
ANTITHROMBOTIC AGENTS	18 (2.4)	14 (1.7)	23 (2.9)	55 (2.3)
HEPARIN GROUP	18 (2.4)	14 (1.7)	23 (2.9)	55 (2.3)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
ANTIVIRALS FOR SYSTEMIC USE	2 (0.3)	2 (0.2)	2 (0.3)	6 (0.3)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
NEURAMINIDASE INHIBITORS		1 (0.1)	1 (0.1)	2 (0.1)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	1 (0.1)			1 (0.0)
OTHER ANTIVIRALS		1 (0.1)		1 (0.0)
BETA BLOCKING AGENTS	18 (2.4)	25 (3.0)	16 (2.0)	59 (2.5)
ALPHA AND BETA BLOCKING AGENTS	13 (1.7)	21 (2.5)	16 (2.0)	50 (2.1)
BETA BLOCKING AGENTS, SELECTIVE	5 (0.7)	4 (0.5)		9 (0.4)
BILE AND LIVER THERAPY	3 (0.4)	4 (0.5)		7 (0.3)
BILE ACIDS AND DERIVATIVES	3 (0.4)	3 (0.4)		6 (0.3)
LIVER THERAPY		1 (0.1)		1 (0.0)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	3 (0.4)	5 (0.6)	4 (0.5)	12 (0.5)
ELECTROLYTE SOLUTIONS		1 (0.1)		1 (0.0)
HYPERTONIC SOLUTIONS	1 (0.1)			1 (0.0)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	1 (0.1)	1 (0.1)	3 (0.4)	5 (0.2)
SOLUTIONS FOR PARENTERAL NUTRITION	1 (0.1)	4 (0.5)	3 (0.4)	8 (0.3)
Not coded	1 (0.1)			1 (0.0)
CALCIUM CHANNEL BLOCKERS	3 (0.4)	1 (0.1)	6 (0.8)	10 (0.4)
DIHYDROPYRIDINE DERIVATIVES	3 (0.4)	1 (0.1)	6 (0.8)	10 (0.4)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1)		2 (0.3)	3 (0.1)
CORTICOSTEROIDS, POTENT (GROUP III)			2 (0.3)	2 (0.1)
CORTICOSTEROIDS, POTENT, OTHER COMBINATIONS	1 (0.1)			1 (0.0)
COUGH AND COLD PREPARATIONS		2 (0.2)		2 (0.1)
EXPECTORANTS		1 (0.1)		1 (0.0)
OPIUM ALKALOIDS AND DERIVATIVES		1 (0.1)		1 (0.0)
DIURETICS	2 (0.3)	2 (0.2)	3 (0.4)	7 (0.3)
SULFONAMIDES, PLAIN	2 (0.3)	2 (0.2)	3 (0.4)	7 (0.3)
DRUGS FOR ACID RELATED DISORDERS	12 (1.6)	35 (4.2)	34 (4.4)	81 (3.4)
ANTACIDS, OTHER COMBINATIONS	1 (0.1)		1 (0.1)	2 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS		2 (0.2)	3 (0.4)	5 (0.2)
H2-RECEPTOR ANTAGONISTS	3 (0.4)	11 (1.3)	3 (0.4)	17 (0.7)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)		4 (0.5)		4 (0.2)
PROTON PUMP INHIBITORS	10 (1.3)	21 (2.5)	28 (3.6)	59 (2.5)
Not coded		1 (0.1)	4 (0.5)	5 (0.2)
DRUGS FOR CONSTIPATION	4 (0.5)	6 (0.7)	6 (0.8)	16 (0.7)
CONTACT LAXATIVES	1 (0.1)		1 (0.1)	2 (0.1)
OSMOTICALLY ACTING LAXATIVES	3 (0.4)	5 (0.6)	5 (0.6)	13 (0.5)
OTHER DRUGS FOR CONSTIPATION		1 (0.1)		1 (0.0)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	10 (1.3)	16 (1.9)	28 (3.6)	54 (2.3)
BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AMMONIUM COMPOUNDS		1 (0.1)	1 (0.1)	2 (0.1)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS		1 (0.1)	9 (1.2)	10 (0.4)
PAPAVERINE AND DERIVATIVES	2 (0.3)	3 (0.4)	7 (0.9)	12 (0.5)
PROPULSIVES	8 (1.0)	11 (1.3)	10 (1.3)	29 (1.2)
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP			1 (0.1)	1 (0.0)
SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM COMPOUNDS			1 (0.1)	1 (0.0)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	2 (0.3)	8 (1.0)	8 (1.0)	18 (0.8)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	1 (0.1)	6 (0.7)	7 (0.9)	14 (0.6)
LEUKOTRIENE RECEPTOR ANTAGONISTS	1 (0.1)	1 (0.1)		2 (0.1)
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES		1 (0.1)	1 (0.1)	2 (0.1)
DRUGS FOR TREATMENT OF BONE DISEASES		1 (0.1)	1 (0.1)	2 (0.1)
BISPHOSPHONATES		1 (0.1)		1 (0.0)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION			1 (0.1)	1 (0.0)
DRUGS USED IN DIABETES	719 (94.1)	788 (95.2)	743 (95.1)	2250 (94.8)
BIGUANIDES	38 (5.0)	39 (4.7)	12 (1.5)	89 (3.8)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	1 (0.1)			1 (0.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES			2 (0.3)	2 (0.1)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	711 (93.1)	773 (93.4)	732 (93.7)	2216 (93.4)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	1 (0.1)	5 (0.6)	12 (1.5)	18 (0.8)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	3 (0.4)	109 (13.2)	3 (0.4)	115 (4.8)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	718 (94.0)	673 (81.3)	7 (0.9)	1398 (58.9)
Not coded	1 (0.1)			1 (0.0)
ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS			1 (0.1)	1 (0.0)
PYRETHRINES, INCL. SYNTHETIC COMPOUNDS			1 (0.1)	1 (0.0)
EMOLLIENTS AND PROTECTIVES			1 (0.1)	1 (0.0)
OTHER EMOLLIENTS AND PROTECTIVES			1 (0.1)	1 (0.0)
GENERAL NUTRIENTS	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES			1 (0.1)	1 (0.0)
OTHER COMBINATIONS OF NUTRIENTS	1 (0.1)	1 (0.1)		2 (0.1)
Not coded		1 (0.1)		1 (0.0)
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS			2 (0.3)	2 (0.1)
IMIDAZOLE DERIVATIVES			2 (0.3)	2 (0.1)
IMMUNE SERA AND IMMUNOGLOBULINS	4 (0.5)	5 (0.6)	6 (0.8)	15 (0.6)
IMMUNOGLOBULINS, NORMAL HUMAN			1 (0.1)	1 (0.0)
SPECIFIC IMMUNOGLOBULINS	4 (0.5)	5 (0.6)	5 (0.6)	14 (0.6)
IMMUNOSUPPRESSANTS	1 (0.1)	3 (0.4)	2 (0.3)	6 (0.3)
OTHER IMMUNOSUPPRESSANTS		3 (0.4)	2 (0.3)	5 (0.2)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	1 (0.1)			1 (0.0)
LIPID MODIFYING AGENTS	1 (0.1)	3 (0.4)	8 (1.0)	12 (0.5)
HMG COA REDUCTASE INHIBITORS	1 (0.1)	3 (0.4)	7 (0.9)	11 (0.5)
OTHER LIPID MODIFYING AGENTS			1 (0.1)	1 (0.0)
MINERAL SUPPLEMENTS	14 (1.8)	47 (5.7)	40 (5.1)	101 (4.3)
CALCIUM	12 (1.6)	28 (3.4)	19 (2.4)	59 (2.5)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	1 (0.1)	10 (1.2)	5 (0.6)	16 (0.7)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
MAGNESIUM	1 (0.1)	11 (1.3)	18 (2.3)	30 (1.3)
OTHER MINERAL PRODUCTS			1 (0.1)	1 (0.0)
SELENIUM			1 (0.1)	1 (0.0)
MULTIPLE ATC, 0	496 (64.9)	674 (81.4)	647 (82.8)	1817 (76.6)
MULTIPLE ATC, 0	496 (64.9)	674 (81.4)	647 (82.8)	1817 (76.6)
NASAL PREPARATIONS		1 (0.1)		1 (0.0)
Not coded		1 (0.1)		1 (0.0)
OPHTHALMOLOGICALS	2 (0.3)	4 (0.5)	17 (2.2)	23 (1.0)
BETA BLOCKING AGENTS			3 (0.4)	3 (0.1)
OTHER OPHTHALMOLOGICALS	1 (0.1)	3 (0.4)	14 (1.8)	18 (0.8)
PARASYMPATHOMIMETICS			1 (0.1)	1 (0.0)
PROSTAGLANDIN ANALOGUES	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)			1 (0.0)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)			1 (0.0)
OTHER DERMATOLOGICAL PREPARATIONS		1 (0.1)	1 (0.1)	2 (0.1)
OTHER DERMATOLOGICALS		1 (0.1)	1 (0.1)	2 (0.1)
OTHER GYNECOLOGICALS	3 (0.4)	4 (0.5)	1 (0.1)	8 (0.3)
ERGOT ALKALOIDS AND OXYTOCIN INCL. ANALOGUES, IN COMBINATION	1 (0.1)			1 (0.0)
OTHER GYNECOLOGICALS	1 (0.1)	3 (0.4)	1 (0.1)	5 (0.2)
PROSTAGLANDINS	1 (0.1)	1 (0.1)		2 (0.1)
OTHER NERVOUS SYSTEM DRUGS		5 (0.6)	1 (0.1)	6 (0.3)
ANTIVERTIGO PREPARATIONS		1 (0.1)		1 (0.0)
DRUGS USED IN NICOTINE DEPENDENCE		4 (0.5)	1 (0.1)	5 (0.2)
PANCREATIC HORMONES	1 (0.1)	4 (0.5)	3 (0.4)	8 (0.3)
GLYCOGENOLYTIC HORMONES	1 (0.1)	4 (0.5)	3 (0.4)	8 (0.3)
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES		2 (0.2)	3 (0.4)	5 (0.2)
ACTH		1 (0.1)		1 (0.0)
OXYTOCIN AND ANALOGUES		1 (0.1)	3 (0.4)	4 (0.2)
PSYCHOANALEPTICS	9 (1.2)	13 (1.6)	9 (1.2)	31 (1.3)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
CENTRALLY ACTING SYMPATHOMIMETICS	1 (0.1)	2 (0.2)	4 (0.5)	7 (0.3)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS		1 (0.1)	1 (0.1)	2 (0.1)
OTHER ANTIDEPRESSANTS		2 (0.2)		2 (0.1)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	8 (1.0)	8 (1.0)	5 (0.6)	21 (0.9)
PSYCHOLEPTICS	2 (0.3)	4 (0.5)	5 (0.6)	11 (0.5)
BENZODIAZEPINE DERIVATIVES	1 (0.1)	2 (0.2)	2 (0.3)	5 (0.2)
BENZODIAZEPINE RELATED DRUGS	1 (0.1)	1 (0.1)		2 (0.1)
MELATONIN RECEPTOR AGONISTS			2 (0.3)	2 (0.1)
OTHER ANTIPSYCHOTICS		1 (0.1)		1 (0.0)
PHENOTHIAZINES WITH ALIPHATIC SIDE-CHAIN			1 (0.1)	1 (0.0)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	7 (0.9)	8 (1.0)	15 (1.9)	30 (1.3)
PREGNADIEN DERIVATIVES	6 (0.8)	5 (0.6)	14 (1.8)	25 (1.1)
PREGNEN (4) DERIVATIVES	1 (0.1)			1 (0.0)
PROGESTERONE RECEPTOR MODULATORS		3 (0.4)	1 (0.1)	4 (0.2)
STOMATOLOGICAL PREPARATIONS		1 (0.1)		1 (0.0)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT		1 (0.1)		1 (0.0)
THROAT PREPARATIONS		1 (0.1)		1 (0.0)
ANTISEPTICS		1 (0.1)		1 (0.0)
THYROID THERAPY	155 (20.3)	209 (25.2)	222 (28.4)	586 (24.7)
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	2 (0.3)	1 (0.1)	3 (0.4)	6 (0.3)
THIOURACILS	4 (0.5)	2 (0.2)	9 (1.2)	15 (0.6)
THYROID HORMONES	149 (19.5)	206 (24.9)	211 (27.0)	566 (23.9)
TONICS	3 (0.4)	9 (1.1)	2 (0.3)	14 (0.6)
Not coded	3 (0.4)	9 (1.1)	2 (0.3)	14 (0.6)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE			3 (0.4)	3 (0.1)
Not coded			3 (0.4)	3 (0.1)
UROLOGICALS	1 (0.1)			1 (0.0)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	1 (0.1)			1 (0.0)
VACCINES	4 (0.5)	7 (0.8)	11 (1.4)	22 (0.9)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
INFLUENZA VACCINES	4 (0.5)	7 (0.8)	10 (1.3)	21 (0.9)
PERTUSSIS VACCINES			1 (0.1)	1 (0.0)
VASOPROTECTIVES	1 (0.1)			1 (0.0)
BIOFLAVONOIDS	1 (0.1)			1 (0.0)
VITAMINS	85 (11.1)	162 (19.6)	162 (20.7)	409 (17.2)
COMBINATIONS OF VITAMINS			1 (0.1)	1 (0.0)
MULTIVITAMINS WITH MINERALS	18 (2.4)	34 (4.1)	13 (1.7)	65 (2.7)
MULTIVITAMINS, OTHER COMBINATIONS	5 (0.7)	18 (2.2)	13 (1.7)	36 (1.5)
VITAMIN B-COMPLEX WITH VITAMIN C		1 (0.1)		1 (0.0)
VITAMIN B-COMPLEX, OTHER COMBINATIONS	2 (0.3)	2 (0.2)	8 (1.0)	12 (0.5)
VITAMIN B-COMPLEX, PLAIN	2 (0.3)	12 (1.4)	1 (0.1)	15 (0.6)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12		1 (0.1)		1 (0.0)
VITAMIN B1, PLAIN	2 (0.3)	2 (0.2)	1 (0.1)	5 (0.2)
VITAMIN D AND ANALOGUES	40 (5.2)	79 (9.5)	98 (12.5)	217 (9.1)
VITAMINS WITH MINERALS	7 (0.9)	13 (1.6)	16 (2.0)	36 (1.5)
VITAMINS, OTHER COMBINATIONS	10 (1.3)	12 (1.4)	23 (2.9)	45 (1.9)
Not coded	2 (0.3)	6 (0.7)	5 (0.6)	13 (0.5)
During third trimester, N (%)				
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	2 (0.3)	2 (0.2)		4 (0.2)
ACE INHIBITORS, PLAIN	2 (0.3)	2 (0.2)		4 (0.2)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	1 (0.1)			1 (0.0)
ALL OTHER THERAPEUTIC PRODUCTS		2 (0.2)	3 (0.4)	5 (0.2)
ANTIDOTES		1 (0.1)		1 (0.0)
DRUGS FOR TREATMENT OF HYPERKALEMIA AND HYPERPHOSPHATEMIA			1 (0.1)	1 (0.0)
MEDICAL GASES			1 (0.1)	1 (0.0)
OTHER THERAPEUTIC PRODUCTS		1 (0.1)	1 (0.1)	2 (0.1)
ANALGESICS	61 (8.0)	96 (11.6)	99 (12.7)	256 (10.8)
ANILIDES	50 (6.5)	83 (10.0)	80 (10.2)	213 (9.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
MORPHINAN DERIVATIVES			1 (0.1)	1 (0.0)
NATURAL OPIUM ALKALOIDS	14 (1.8)	24 (2.9)	34 (4.4)	72 (3.0)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	11 (1.4)	11 (1.3)	14 (1.8)	36 (1.5)
OTHER ANALGESICS AND ANTIPYRETICS	3 (0.4)	8 (1.0)	14 (1.8)	25 (1.1)
OTHER OPIOIDS	4 (0.5)	4 (0.5)	5 (0.6)	13 (0.5)
PHENYLPIPERIDINE DERIVATIVES	1 (0.1)	3 (0.4)	1 (0.1)	5 (0.2)
PYRAZOLONES	4 (0.5)	6 (0.7)	3 (0.4)	13 (0.5)
SELECTIVE SEROTONIN (5HT1) AGONISTS		1 (0.1)	3 (0.4)	4 (0.2)
Not coded	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
ANESTHETICS	20 (2.6)	32 (3.9)	51 (6.5)	103 (4.3)
AMIDES	5 (0.7)	19 (2.3)	38 (4.9)	62 (2.6)
OPIOID ANESTHETICS	1 (0.1)		1 (0.1)	2 (0.1)
OTHER GENERAL ANESTHETICS	6 (0.8)	7 (0.8)	6 (0.8)	19 (0.8)
Not coded	9 (1.2)	10 (1.2)	10 (1.3)	29 (1.2)
ANTI-ACNE PREPARATIONS		1 (0.1)	1 (0.1)	2 (0.1)
ANTIINFECTIVES FOR TREATMENT OF ACNE		1 (0.1)		1 (0.0)
RETINOIDS FOR TOPICAL USE IN ACNE			1 (0.1)	1 (0.0)
ANTI-PARKINSON DRUGS			1 (0.1)	1 (0.0)
MONOAMINE OXIDASE B INHIBITORS			1 (0.1)	1 (0.0)
ANTIANEMIC PREPARATIONS	55 (7.2)	101 (12.2)	121 (15.5)	277 (11.7)
FOLIC ACID AND DERIVATIVES	2 (0.3)	8 (1.0)	2 (0.3)	12 (0.5)
IRON BIVALENT, ORAL PREPARATIONS	33 (4.3)	55 (6.6)	73 (9.3)	161 (6.8)
IRON IN COMBINATION WITH FOLIC ACID	8 (1.0)	4 (0.5)	24 (3.1)	36 (1.5)
IRON IN OTHER COMBINATIONS	2 (0.3)	5 (0.6)	2 (0.3)	9 (0.4)
IRON TRIVALENT, ORAL PREPARATIONS		2 (0.2)	6 (0.8)	8 (0.3)
IRON, PARENTERAL PREPARATIONS	1 (0.1)	3 (0.4)	2 (0.3)	6 (0.3)
OTHER ANTIANEMIC PREPARATIONS		1 (0.1)	1 (0.1)	2 (0.1)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	11 (1.4)	31 (3.7)	20 (2.6)	62 (2.6)
Not coded		4 (0.5)	2 (0.3)	6 (0.3)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
ANTIBACTERIALS FOR SYSTEMIC USE	46 (6.0)	73 (8.8)	71 (9.1)	190 (8.0)
BETA-LACTAMASE INHIBITORS		1 (0.1)		1 (0.0)
BETA-LACTAMASE RESISTANT PENICILLINS	2 (0.3)	2 (0.2)		4 (0.2)
BETA-LACTAMASE SENSITIVE PENICILLINS	2 (0.3)	3 (0.4)	1 (0.1)	6 (0.3)
CARBAPENEMS		2 (0.2)		2 (0.1)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	22 (2.9)	19 (2.3)	12 (1.5)	53 (2.2)
FIRST-GENERATION CEPHALOSPORINS	12 (1.6)	23 (2.8)	40 (5.1)	75 (3.2)
GLYCOPEPTIDE ANTIBACTERIALS		1 (0.1)		1 (0.0)
MACROLIDES	1 (0.1)			1 (0.0)
MONOBACTAMS		1 (0.1)		1 (0.0)
NITROFURAN DERIVATIVES	3 (0.4)	7 (0.8)	6 (0.8)	16 (0.7)
OTHER ANTIBACTERIALS	1 (0.1)	2 (0.2)	2 (0.3)	5 (0.2)
PENICILLINS WITH EXTENDED SPECTRUM	8 (1.0)	18 (2.2)	17 (2.2)	43 (1.8)
SECOND-GENERATION CEPHALOSPORINS		1 (0.1)	2 (0.3)	3 (0.1)
THIRD-GENERATION CEPHALOSPORINS	1 (0.1)	3 (0.4)		4 (0.2)
TRIMETHOPRIM AND DERIVATIVES	2 (0.3)	2 (0.2)		4 (0.2)
Not coded		1 (0.1)	1 (0.1)	2 (0.1)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE		1 (0.1)		1 (0.0)
ANTIVIRALS		1 (0.1)		1 (0.0)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	1 (0.1)	1 (0.1)	7 (0.9)	9 (0.4)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (0.1)	1 (0.1)	6 (0.8)	8 (0.3)
ANTIDIARRHEAL MICROORGANISMS			1 (0.1)	1 (0.0)
ANTIEMETICS AND ANTINAUSEANTS	26 (3.4)	33 (4.0)	37 (4.7)	96 (4.0)
OTHER ANTIEMETICS	1 (0.1)	2 (0.2)	3 (0.4)	6 (0.3)
SEROTONIN (5HT3) ANTAGONISTS	25 (3.3)	31 (3.7)	34 (4.4)	90 (3.8)
ANTIEPILEPTICS	6 (0.8)	4 (0.5)	2 (0.3)	12 (0.5)
FATTY ACID DERIVATIVES	3 (0.4)	2 (0.2)		5 (0.2)
OTHER ANTIEPILEPTICS	3 (0.4)	3 (0.4)	2 (0.3)	8 (0.3)
ANTIFUNGALS FOR DERMATOLOGICAL USE		1 (0.1)		1 (0.0)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
OTHER ANTIFUNGALS FOR TOPICAL USE		1 (0.1)		1 (0.0)
ANTIHEMORRHAGICS			2 (0.3)	2 (0.1)
FIBRINOGEN			2 (0.3)	2 (0.1)
ANTIHISTAMINES FOR SYSTEMIC USE	6 (0.8)	6 (0.7)	8 (1.0)	20 (0.8)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	2 (0.3)	2 (0.2)	3 (0.4)	7 (0.3)
PHENOTHIAZINE DERIVATIVES			2 (0.3)	2 (0.1)
PIPERAZINE DERIVATIVES	2 (0.3)	1 (0.1)		3 (0.1)
SUBSTITUTED ALKYLAMINES	2 (0.3)	3 (0.4)	3 (0.4)	8 (0.3)
ANTIHYPERTENSIVES	38 (5.0)	79 (9.5)	64 (8.2)	181 (7.6)
ALPHA-ADRENORECEPTOR ANTAGONISTS		1 (0.1)	3 (0.4)	4 (0.2)
HYDRAZINOPHTHALAZINE DERIVATIVES	1 (0.1)	4 (0.5)	5 (0.6)	10 (0.4)
METHYLDOPA	37 (4.8)	77 (9.3)	57 (7.3)	171 (7.2)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	1 (0.1)		1 (0.1)	2 (0.1)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	1 (0.1)			1 (0.0)
FENAMATES			1 (0.1)	1 (0.0)
ANTIMYCOBACTERIALS		1 (0.1)		1 (0.0)
ANTIBIOTICS		1 (0.1)		1 (0.0)
OTHER DRUGS FOR TREATMENT OF TUBERCULOSIS		1 (0.1)		1 (0.0)
THIOCARBAMIDE DERIVATIVES		1 (0.1)		1 (0.0)
ANTIMYCOTICS FOR SYSTEMIC USE		1 (0.1)		1 (0.0)
TRIAZOLE DERIVATIVES		1 (0.1)		1 (0.0)
ANTINEOPLASTIC AGENTS		1 (0.1)		1 (0.0)
PURINE ANALOGUES		1 (0.1)		1 (0.0)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.		1 (0.1)		1 (0.0)
OTHER ANTIPRURITICS		1 (0.1)		1 (0.0)
ANTIPSORIATICS			1 (0.1)	1 (0.0)
OTHER ANTIPSORIATICS FOR TOPICAL USE			1 (0.1)	1 (0.0)
ANTISEPTICS AND DISINFECTANTS	1 (0.1)			1 (0.0)
OTHER ANTISEPTICS AND DISINFECTANTS	1 (0.1)			1 (0.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
ANTITHROMBOTIC AGENTS	41 (5.4)	49 (5.9)	65 (8.3)	155 (6.5)
HEPARIN GROUP	41 (5.4)	49 (5.9)	65 (8.3)	155 (6.5)
ANTIVIRALS FOR SYSTEMIC USE	2 (0.3)	4 (0.5)	2 (0.3)	8 (0.3)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
NEURAMINIDASE INHIBITORS		3 (0.4)	1 (0.1)	4 (0.2)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	1 (0.1)			1 (0.0)
OTHER ANTIVIRALS		1 (0.1)		1 (0.0)
BETA BLOCKING AGENTS	42 (5.5)	78 (9.4)	44 (5.6)	164 (6.9)
ALPHA AND BETA BLOCKING AGENTS	36 (4.7)	71 (8.6)	43 (5.5)	150 (6.3)
BETA BLOCKING AGENTS, NON-SELECTIVE	1 (0.1)		1 (0.1)	2 (0.1)
BETA BLOCKING AGENTS, SELECTIVE	5 (0.7)	7 (0.8)	1 (0.1)	13 (0.5)
BILE AND LIVER THERAPY	3 (0.4)	11 (1.3)	4 (0.5)	18 (0.8)
BILE ACIDS AND DERIVATIVES	3 (0.4)	10 (1.2)	4 (0.5)	17 (0.7)
LIVER THERAPY		1 (0.1)		1 (0.0)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	18 (2.4)	39 (4.7)	55 (7.0)	112 (4.7)
BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS		1 (0.1)	3 (0.4)	4 (0.2)
ELECTROLYTE SOLUTIONS			1 (0.1)	1 (0.0)
HYPERTONIC SOLUTIONS	1 (0.1)	2 (0.2)	3 (0.4)	6 (0.3)
OTHER BLOOD PRODUCTS	1 (0.1)		1 (0.1)	2 (0.1)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	10 (1.3)	32 (3.9)	41 (5.2)	83 (3.5)
SOLUTIONS FOR PARENTERAL NUTRITION	6 (0.8)	22 (2.7)	37 (4.7)	65 (2.7)
Not coded	1 (0.1)	1 (0.1)		2 (0.1)
CALCIUM CHANNEL BLOCKERS	2 (0.3)	5 (0.6)	13 (1.7)	20 (0.8)
DIHYDROPYRIDINE DERIVATIVES	2 (0.3)	5 (0.6)	13 (1.7)	20 (0.8)
CARDIAC THERAPY			2 (0.3)	2 (0.1)
OTHER CARDIAC PREPARATIONS			2 (0.3)	2 (0.1)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
CORTICOSTEROIDS, POTENT (GROUP III)		1 (0.1)	2 (0.3)	3 (0.1)
CORTICOSTEROIDS, POTENT, OTHER COMBINATIONS	1 (0.1)			1 (0.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
COUGH AND COLD PREPARATIONS		1 (0.1)		1 (0.0)
EXPECTORANTS		1 (0.1)		1 (0.0)
DIURETICS	2 (0.3)	5 (0.6)	4 (0.5)	11 (0.5)
SULFONAMIDES, PLAIN	2 (0.3)	3 (0.4)	4 (0.5)	9 (0.4)
THIAZIDES, PLAIN		2 (0.2)		2 (0.1)
DRUGS FOR ACID RELATED DISORDERS	39 (5.1)	63 (7.6)	62 (7.9)	164 (6.9)
ANTACIDS, OTHER COMBINATIONS	1 (0.1)		1 (0.1)	2 (0.1)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS		2 (0.2)	3 (0.4)	5 (0.2)
H2-RECEPTOR ANTAGONISTS	30 (3.9)	42 (5.1)	34 (4.4)	106 (4.5)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	2 (0.3)	3 (0.4)	1 (0.1)	6 (0.3)
PROTON PUMP INHIBITORS	13 (1.7)	20 (2.4)	29 (3.7)	62 (2.6)
Not coded		3 (0.4)	4 (0.5)	7 (0.3)
DRUGS FOR CONSTIPATION	5 (0.7)	8 (1.0)	5 (0.6)	18 (0.8)
CONTACT LAXATIVES	1 (0.1)		1 (0.1)	2 (0.1)
OSMOTICALLY ACTING LAXATIVES	4 (0.5)	7 (0.8)	4 (0.5)	15 (0.6)
OTHER DRUGS FOR CONSTIPATION		1 (0.1)		1 (0.0)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	11 (1.4)	27 (3.3)	51 (6.5)	89 (3.8)
BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AMMONIUM COMPOUNDS		2 (0.2)	3 (0.4)	5 (0.2)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	3 (0.4)	13 (1.6)	26 (3.3)	42 (1.8)
PAPAVERINE AND DERIVATIVES	1 (0.1)	3 (0.4)	10 (1.3)	14 (0.6)
PROPULSIVES	7 (0.9)	9 (1.1)	18 (2.3)	34 (1.4)
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP			1 (0.1)	1 (0.0)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	2 (0.3)	10 (1.2)	8 (1.0)	20 (0.8)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	1 (0.1)	7 (0.8)	7 (0.9)	15 (0.6)
LEUKOTRIENE RECEPTOR ANTAGONISTS	1 (0.1)	1 (0.1)		2 (0.1)
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES		1 (0.1)	1 (0.1)	2 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
XANTHINES		1 (0.1)		1 (0.0)
DRUGS FOR TREATMENT OF BONE DISEASES		1 (0.1)	1 (0.1)	2 (0.1)
BISPHOSPHONATES		1 (0.1)		1 (0.0)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION			1 (0.1)	1 (0.0)
DRUGS USED IN DIABETES	696 (91.1)	744 (89.9)	709 (90.8)	2149 (90.6)
BIGUANIDES	33 (4.3)	38 (4.6)	12 (1.5)	83 (3.5)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	1 (0.1)			1 (0.0)
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES			1 (0.1)	1 (0.0)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	691 (90.4)	733 (88.5)	699 (89.5)	2123 (89.5)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING		5 (0.6)	9 (1.2)	14 (0.6)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	3 (0.4)	100 (12.1)	3 (0.4)	106 (4.5)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	689 (90.2)	622 (75.1)	7 (0.9)	1318 (55.5)
Not coded	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
EMOLLIENTS AND PROTECTIVES		2 (0.2)	2 (0.3)	4 (0.2)
OTHER EMOLLIENTS AND PROTECTIVES		2 (0.2)	1 (0.1)	3 (0.1)
ZINC PRODUCTS			1 (0.1)	1 (0.0)
GENERAL NUTRIENTS	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES			1 (0.1)	1 (0.0)
OTHER COMBINATIONS OF NUTRIENTS	1 (0.1)	1 (0.1)		2 (0.1)
Not coded		1 (0.1)		1 (0.0)
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
IMIDAZOLE DERIVATIVES		1 (0.1)	2 (0.3)	3 (0.1)
OTHER ANTIINFECTIVES AND ANTISEPTICS	1 (0.1)			1 (0.0)
IMMUNE SERA AND IMMUNOGLOBULINS	5 (0.7)	8 (1.0)	13 (1.7)	26 (1.1)
IMMUNOGLOBULINS, NORMAL HUMAN	1 (0.1)		2 (0.3)	3 (0.1)
SPECIFIC IMMUNOGLOBULINS	4 (0.5)	8 (1.0)	11 (1.4)	23 (1.0)
IMMUNOSUPPRESSANTS	1 (0.1)	3 (0.4)	2 (0.3)	6 (0.3)
OTHER IMMUNOSUPPRESSANTS		3 (0.4)	2 (0.3)	5 (0.2)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	1 (0.1)			1 (0.0)
LIPID MODIFYING AGENTS	1 (0.1)	4 (0.5)	6 (0.8)	11 (0.5)
HMG COA REDUCTASE INHIBITORS	1 (0.1)	3 (0.4)	5 (0.6)	9 (0.4)
OTHER LIPID MODIFYING AGENTS		1 (0.1)	1 (0.1)	2 (0.1)
MINERAL SUPPLEMENTS	17 (2.2)	53 (6.4)	49 (6.3)	119 (5.0)
CALCIUM	11 (1.4)	29 (3.5)	19 (2.4)	59 (2.5)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	1 (0.1)	10 (1.2)	6 (0.8)	17 (0.7)
MAGNESIUM	5 (0.7)	16 (1.9)	27 (3.5)	48 (2.0)
SELENIUM			2 (0.3)	2 (0.1)
MULTIPLE ATC, 0	449 (58.8)	609 (73.6)	584 (74.8)	1642 (69.2)
MULTIPLE ATC, 0	449 (58.8)	609 (73.6)	584 (74.8)	1642 (69.2)
MUSCLE RELAXANTS	1 (0.1)		3 (0.4)	4 (0.2)
CHOLINE DERIVATIVES	1 (0.1)		2 (0.3)	3 (0.1)
OTHER QUATERNARY AMMONIUM COMPOUNDS			2 (0.3)	2 (0.1)
NASAL PREPARATIONS		1 (0.1)		1 (0.0)
Not coded		1 (0.1)		1 (0.0)
OPHTHALMOLOGICALS	2 (0.3)	4 (0.5)	14 (1.8)	20 (0.8)
BETA BLOCKING AGENTS			2 (0.3)	2 (0.1)
OTHER ANTIINFECTIVES			1 (0.1)	1 (0.0)
OTHER OPHTHALMOLOGICALS	1 (0.1)	3 (0.4)	11 (1.4)	15 (0.6)
PARASYMPATHOMIMETICS			1 (0.1)	1 (0.0)
PROSTAGLANDIN ANALOGUES	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)			1 (0.0)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)			1 (0.0)
OTHER DERMATOLOGICAL PREPARATIONS			1 (0.1)	1 (0.0)
OTHER DERMATOLOGICALS			1 (0.1)	1 (0.0)
OTHER GYNECOLOGICALS	24 (3.1)	34 (4.1)	46 (5.9)	104 (4.4)
ERGOT ALKALOIDS			1 (0.1)	1 (0.0)
ERGOT ALKALOIDS AND OXYTOCIN INCL. ANALOGUES, IN COMBINATION	3 (0.4)	4 (0.5)	1 (0.1)	8 (0.3)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
OTHER GYNECOLOGICALS	8 (1.0)	5 (0.6)	3 (0.4)	16 (0.7)
PROSTAGLANDINS	14 (1.8)	27 (3.3)	41 (5.2)	82 (3.5)
SYMPATHOMIMETICS, LABOUR REPRESSANTS			1 (0.1)	1 (0.0)
OTHER NERVOUS SYSTEM DRUGS		5 (0.6)	2 (0.3)	7 (0.3)
ANTIVERTIGO PREPARATIONS		1 (0.1)		1 (0.0)
DRUGS USED IN NICOTINE DEPENDENCE		4 (0.5)	2 (0.3)	6 (0.3)
OTOLOGICALS		1 (0.1)		1 (0.0)
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION		1 (0.1)		1 (0.0)
PANCREATIC HORMONES	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
GLYCOGENOLYTIC HORMONES	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES	31 (4.1)	43 (5.2)	71 (9.1)	145 (6.1)
OXYTOCIN AND ANALOGUES	31 (4.1)	43 (5.2)	71 (9.1)	145 (6.1)
PSYCHOANALEPTICS	9 (1.2)	12 (1.4)	7 (0.9)	28 (1.2)
CENTRALLY ACTING SYMPATHOMIMETICS	1 (0.1)	2 (0.2)	3 (0.4)	6 (0.3)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS		1 (0.1)	1 (0.1)	2 (0.1)
OTHER ANTIDEPRESSANTS		1 (0.1)		1 (0.0)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	8 (1.0)	8 (1.0)	4 (0.5)	20 (0.8)
PSYCHOLEPTICS	6 (0.8)	3 (0.4)	6 (0.8)	15 (0.6)
BENZODIAZEPINE DERIVATIVES	6 (0.8)	1 (0.1)	1 (0.1)	8 (0.3)
BENZODIAZEPINE RELATED DRUGS		1 (0.1)	2 (0.3)	3 (0.1)
MELATONIN RECEPTOR AGONISTS			2 (0.3)	2 (0.1)
OTHER ANTIPSYCHOTICS		1 (0.1)		1 (0.0)
PHENOTHIAZINES WITH ALIPHATIC SIDE-CHAIN			1 (0.1)	1 (0.0)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	7 (0.9)	2 (0.2)	9 (1.2)	18 (0.8)
PREGNADIEN DERIVATIVES	5 (0.7)	2 (0.2)	9 (1.2)	16 (0.7)
PREGNEN (4) DERIVATIVES	1 (0.1)			1 (0.0)
PROGESTERONE RECEPTOR MODULATORS	1 (0.1)			1 (0.0)
THROAT PREPARATIONS		1 (0.1)		1 (0.0)
ANTISEPTICS		1 (0.1)		1 (0.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
THYROID THERAPY	153 (20.0)	201 (24.3)	217 (27.8)	571 (24.1)
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	2 (0.3)	1 (0.1)	3 (0.4)	6 (0.3)
THIOURACILS	4 (0.5)	1 (0.1)	7 (0.9)	12 (0.5)
THYROID HORMONES	147 (19.2)	199 (24.0)	207 (26.5)	553 (23.3)
TONICS	3 (0.4)	7 (0.8)	2 (0.3)	12 (0.5)
Not coded	3 (0.4)	7 (0.8)	2 (0.3)	12 (0.5)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE		2 (0.2)	2 (0.3)	4 (0.2)
Not coded		2 (0.2)	2 (0.3)	4 (0.2)
UROLOGICALS	1 (0.1)			1 (0.0)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	1 (0.1)			1 (0.0)
VACCINES	3 (0.4)	8 (1.0)	4 (0.5)	15 (0.6)
BACTERIAL AND VIRAL VACCINES, COMBINED	2 (0.3)	3 (0.4)	1 (0.1)	6 (0.3)
INFLUENZA VACCINES		4 (0.5)	3 (0.4)	7 (0.3)
PERTUSSIS VACCINES	1 (0.1)	1 (0.1)		2 (0.1)
TETANUS VACCINES		1 (0.1)		1 (0.0)
VASOPROTECTIVES	2 (0.3)	1 (0.1)	5 (0.6)	8 (0.3)
BIOFLAVONOIDS	1 (0.1)	1 (0.1)		2 (0.1)
LOCAL ANESTHETICS	1 (0.1)		3 (0.4)	4 (0.2)
OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS ANDANAL FISSURES FOR TOPICAL USE	1 (0.1)		4 (0.5)	5 (0.2)
VITAMINS	80 (10.5)	154 (18.6)	149 (19.1)	383 (16.1)
COMBINATIONS OF VITAMINS			1 (0.1)	1 (0.0)
MULTIVITAMINS WITH MINERALS	17 (2.2)	32 (3.9)	13 (1.7)	62 (2.6)
MULTIVITAMINS, OTHER COMBINATIONS	4 (0.5)	16 (1.9)	15 (1.9)	35 (1.5)
VITAMIN B-COMPLEX WITH VITAMIN C	1 (0.1)	1 (0.1)		2 (0.1)
VITAMIN B-COMPLEX, OTHER COMBINATIONS	2 (0.3)	1 (0.1)	7 (0.9)	10 (0.4)
VITAMIN B-COMPLEX, PLAIN	2 (0.3)	12 (1.4)	1 (0.1)	15 (0.6)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12		1 (0.1)		1 (0.0)
VITAMIN B1, PLAIN	1 (0.1)		1 (0.1)	2 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary – FAS MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
VITAMIN D AND ANALOGUES	37 (4.8)	73 (8.8)	85 (10.9)	195 (8.2)
VITAMINS WITH MINERALS	7 (0.9)	13 (1.6)	16 (2.0)	36 (1.5)
VITAMINS, OTHER COMBINATIONS	10 (1.3)	13 (1.6)	20 (2.6)	43 (1.8)
Not coded	2 (0.3)	6 (0.7)	5 (0.6)	13 (0.5)

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14.1.29 Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
Number of subjects	727	730	1457
Medication during Pregnancy			
At any time during pregnancy, N (%)			
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	2 (0.3)	6 (0.8)	8 (0.5)
ACE INHIBITORS AND DIURETICS		1 (0.1)	1 (0.1)
ACE INHIBITORS, PLAIN	2 (0.3)	5 (0.7)	7 (0.5)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN		1 (0.1)	1 (0.1)
ALL OTHER THERAPEUTIC PRODUCTS		1 (0.1)	1 (0.1)
ANTIDOTES		1 (0.1)	1 (0.1)
ANALGESICS	69 (9.5)	91 (12.5)	160 (11.0)
ANILIDES	56 (7.7)	79 (10.8)	135 (9.3)
NATURAL OPIUM ALKALOIDS	13 (1.8)	21 (2.9)	34 (2.3)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	10 (1.4)	9 (1.2)	19 (1.3)
OTHER ANALGESICS AND ANTIPYRETICS		1 (0.1)	1 (0.1)
OTHER OPIOIDS	3 (0.4)	3 (0.4)	6 (0.4)
PHENYLPIPERIDINE DERIVATIVES	3 (0.4)	4 (0.5)	7 (0.5)
PYRAZOLONES	4 (0.6)	5 (0.7)	9 (0.6)
SELECTIVE SEROTONIN (5HT1) AGONISTS		2 (0.3)	2 (0.1)
Not coded	3 (0.4)	3 (0.4)	6 (0.4)
ANESTHETICS	17 (2.3)	19 (2.6)	36 (2.5)
AMIDES	4 (0.6)	7 (1.0)	11 (0.8)
OPIOID ANESTHETICS	1 (0.1)		1 (0.1)
OTHER GENERAL ANESTHETICS	6 (0.8)	2 (0.3)	8 (0.5)
Not coded	9 (1.2)	10 (1.4)	19 (1.3)
ANTI-ACNE PREPARATIONS		1 (0.1)	1 (0.1)
ANTIINFECTIVES FOR TREATMENT OF ACNE		1 (0.1)	1 (0.1)
ANTIANEMIC PREPARATIONS	60 (8.3)	102 (14.0)	162 (11.1)
FOLIC ACID AND DERIVATIVES	3 (0.4)	9 (1.2)	12 (0.8)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
IRON BIVALENT, ORAL PREPARATIONS	35 (4.8)	49 (6.7)	84 (5.8)
IRON IN COMBINATION WITH FOLIC ACID	6 (0.8)	3 (0.4)	9 (0.6)
IRON IN OTHER COMBINATIONS	2 (0.3)	9 (1.2)	11 (0.8)
IRON TRIVALENT, ORAL PREPARATIONS		4 (0.5)	4 (0.3)
IRON, PARENTERAL PREPARATIONS	2 (0.3)	1 (0.1)	3 (0.2)
OTHER ANTIANEMIC PREPARATIONS		1 (0.1)	1 (0.1)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	14 (1.9)	40 (5.5)	54 (3.7)
Not coded		4 (0.5)	4 (0.3)
ANTIBACTERIALS FOR SYSTEMIC USE	61 (8.4)	85 (11.6)	146 (10.0)
BETA-LACTAMASE INHIBITORS		1 (0.1)	1 (0.1)
BETA-LACTAMASE RESISTANT PENICILLINS	2 (0.3)	3 (0.4)	5 (0.3)
BETA-LACTAMASE SENSITIVE PENICILLINS	2 (0.3)	8 (1.1)	10 (0.7)
CARBAPENEMS		2 (0.3)	2 (0.1)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	22 (3.0)	23 (3.2)	45 (3.1)
FIRST-GENERATION CEPHALOSPORINS	12 (1.7)	17 (2.3)	29 (2.0)
GLYCOPEPTIDE ANTIBACTERIALS		1 (0.1)	1 (0.1)
MONOBACTAMS		1 (0.1)	1 (0.1)
NITROFURAN DERIVATIVES	5 (0.7)	11 (1.5)	16 (1.1)
OTHER ANTIBACTERIALS	4 (0.6)	8 (1.1)	12 (0.8)
PENICILLINS WITH EXTENDED SPECTRUM	20 (2.8)	24 (3.3)	44 (3.0)
SECOND-GENERATION CEPHALOSPORINS	2 (0.3)	1 (0.1)	3 (0.2)
THIRD-GENERATION CEPHALOSPORINS	3 (0.4)	3 (0.4)	6 (0.4)
TRIMETHOPRIM AND DERIVATIVES	3 (0.4)	2 (0.3)	5 (0.3)
Not coded		1 (0.1)	1 (0.1)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE		1 (0.1)	1 (0.1)
ANTIVIRALS		1 (0.1)	1 (0.1)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	1 (0.1)	1 (0.1)	2 (0.1)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (0.1)	1 (0.1)	2 (0.1)
ANTIEMETICS AND ANTINAUSEANTS	26 (3.6)	38 (5.2)	64 (4.4)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
OTHER ANTIEMETICS	3 (0.4)	5 (0.7)	8 (0.5)
SEROTONIN (5HT3) ANTAGONISTS	24 (3.3)	33 (4.5)	57 (3.9)
ANTIEPILEPTICS	4 (0.6)	4 (0.5)	8 (0.5)
FATTY ACID DERIVATIVES	2 (0.3)	2 (0.3)	4 (0.3)
OTHER ANTIEPILEPTICS	2 (0.3)	3 (0.4)	5 (0.3)
ANTIFUNGALS FOR DERMATOLOGICAL USE		1 (0.1)	1 (0.1)
OTHER ANTIFUNGALS FOR TOPICAL USE		1 (0.1)	1 (0.1)
ANTIHEMORRHAGICS		1 (0.1)	1 (0.1)
VITAMIN K		1 (0.1)	1 (0.1)
ANTIHISTAMINES FOR SYSTEMIC USE	6 (0.8)	8 (1.1)	14 (1.0)
AMINOALKYL ETHERS		1 (0.1)	1 (0.1)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	3 (0.4)	1 (0.1)	4 (0.3)
PIPERAZINE DERIVATIVES	1 (0.1)	1 (0.1)	2 (0.1)
SUBSTITUTED ALKYLAMINES	2 (0.3)	5 (0.7)	7 (0.5)
ANTIHYPERTENSIVES	44 (6.1)	75 (10.3)	119 (8.2)
ALPHA-ADRENORECEPTOR ANTAGONISTS		1 (0.1)	1 (0.1)
HYDRAZINOPHTHALAZINE DERIVATIVES	1 (0.1)	4 (0.5)	5 (0.3)
METHYLDOPA	43 (5.9)	73 (10.0)	116 (8.0)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	2 (0.3)		2 (0.1)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	1 (0.1)		1 (0.1)
FENAMATES	1 (0.1)		1 (0.1)
ANTIMYCOBACTERIALS		1 (0.1)	1 (0.1)
ANTIBIOTICS		1 (0.1)	1 (0.1)
OTHER DRUGS FOR TREATMENT OF TUBERCULOSIS		1 (0.1)	1 (0.1)
THIOCARBAMIDE DERIVATIVES		1 (0.1)	1 (0.1)
ANTIMYCOTICS FOR SYSTEMIC USE		1 (0.1)	1 (0.1)
TRIAZOLE DERIVATIVES		1 (0.1)	1 (0.1)
ANTINEOPLASTIC AGENTS		1 (0.1)	1 (0.1)
PURINE ANALOGUES		1 (0.1)	1 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.		1 (0.1)	1 (0.1)
OTHER ANTIPRURITICS		1 (0.1)	1 (0.1)
ANTISEPTICS AND DISINFECTANTS	1 (0.1)		1 (0.1)
OTHER ANTISEPTICS AND DISINFECTANTS	1 (0.1)		1 (0.1)
ANTITHROMBOTIC AGENTS	42 (5.8)	45 (6.2)	87 (6.0)
HEPARIN GROUP	42 (5.8)	45 (6.2)	87 (6.0)
ANTIVIRALS FOR SYSTEMIC USE	2 (0.3)	4 (0.5)	6 (0.4)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS	1 (0.1)	1 (0.1)	2 (0.1)
NEURAMINIDASE INHIBITORS		3 (0.4)	3 (0.2)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	1 (0.1)		1 (0.1)
OTHER ANTIVIRALS		1 (0.1)	1 (0.1)
BETA BLOCKING AGENTS	43 (5.9)	70 (9.6)	113 (7.8)
ALPHA AND BETA BLOCKING AGENTS	38 (5.2)	65 (8.9)	103 (7.1)
BETA BLOCKING AGENTS, SELECTIVE	5 (0.7)	5 (0.7)	10 (0.7)
BILE AND LIVER THERAPY	2 (0.3)	12 (1.6)	14 (1.0)
BILE ACIDS AND DERIVATIVES	2 (0.3)	11 (1.5)	13 (0.9)
LIVER THERAPY		1 (0.1)	1 (0.1)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	17 (2.3)	25 (3.4)	42 (2.9)
BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS		1 (0.1)	1 (0.1)
ELECTROLYTE SOLUTIONS		1 (0.1)	1 (0.1)
HYPERTONIC SOLUTIONS	1 (0.1)	2 (0.3)	3 (0.2)
OTHER BLOOD PRODUCTS	1 (0.1)		1 (0.1)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	10 (1.4)	16 (2.2)	26 (1.8)
SOLUTIONS FOR PARENTERAL NUTRITION	5 (0.7)	12 (1.6)	17 (1.2)
Not coded	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM CHANNEL BLOCKERS	4 (0.6)	5 (0.7)	9 (0.6)
DIHYDROPYRIDINE DERIVATIVES	4 (0.6)	5 (0.7)	9 (0.6)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1)	3 (0.4)	4 (0.3)
CORTICOSTEROIDS, POTENT (GROUP III)		1 (0.1)	1 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
CORTICOSTEROIDS, POTENT, COMBINATIONS WITH ANTIBIOTICS		1 (0.1)	1 (0.1)
CORTICOSTEROIDS, POTENT, OTHER COMBINATIONS	1 (0.1)		1 (0.1)
Not coded		1 (0.1)	1 (0.1)
COUGH AND COLD PREPARATIONS		2 (0.3)	2 (0.1)
EXPECTORANTS		1 (0.1)	1 (0.1)
OPIUM ALKALOIDS AND DERIVATIVES		1 (0.1)	1 (0.1)
DIURETICS	3 (0.4)	6 (0.8)	9 (0.6)
SULFONAMIDES, PLAIN	3 (0.4)	4 (0.5)	7 (0.5)
THIAZIDES, PLAIN		2 (0.3)	2 (0.1)
DRUGS FOR ACID RELATED DISORDERS	38 (5.2)	63 (8.6)	101 (6.9)
ANTACIDS, OTHER COMBINATIONS	1 (0.1)		1 (0.1)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS		3 (0.4)	3 (0.2)
H2-RECEPTOR ANTAGONISTS	28 (3.9)	39 (5.3)	67 (4.6)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	1 (0.1)	3 (0.4)	4 (0.3)
PROTON PUMP INHIBITORS	13 (1.8)	24 (3.3)	37 (2.5)
Not coded		1 (0.1)	1 (0.1)
DRUGS FOR CONSTIPATION	5 (0.7)	9 (1.2)	14 (1.0)
CONTACT LAXATIVES	1 (0.1)	1 (0.1)	2 (0.1)
OSMOTICALLY ACTING LAXATIVES	4 (0.6)	7 (1.0)	11 (0.8)
OTHER DRUGS FOR CONSTIPATION		1 (0.1)	1 (0.1)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	15 (2.1)	23 (3.2)	38 (2.6)
BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AMMONIUM COMPOUNDS		1 (0.1)	1 (0.1)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	1 (0.1)	4 (0.5)	5 (0.3)
PAPAVERINE AND DERIVATIVES	2 (0.3)	3 (0.4)	5 (0.3)
PROPULSIVES	13 (1.8)	15 (2.1)	28 (1.9)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	2 (0.3)	8 (1.1)	10 (0.7)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	1 (0.1)	6 (0.8)	7 (0.5)
LEUKOTRIENE RECEPTOR ANTAGONISTS	1 (0.1)	1 (0.1)	2 (0.1)
XANTHINES		1 (0.1)	1 (0.1)
DRUGS USED IN DIABETES	727 (100)	730 (100)	1457 (100)
BIGUANIDES	44 (6.1)	38 (5.2)	82 (5.6)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	1 (0.1)		1 (0.1)
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES		1 (0.1)	1 (0.1)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	721 (99.2)	723 (99.0)	1444 (99.1)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING		96 (13.2)	96 (6.6)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	727 (100)	634 (86.8)	1361 (93.4)
Not coded	1 (0.1)		1 (0.1)
GENERAL NUTRIENTS	1 (0.1)	2 (0.3)	3 (0.2)
OTHER COMBINATIONS OF NUTRIENTS	1 (0.1)	1 (0.1)	2 (0.1)
Not coded		1 (0.1)	1 (0.1)
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	1 (0.1)	1 (0.1)	2 (0.1)
IMIDAZOLE DERIVATIVES		1 (0.1)	1 (0.1)
OTHER ANTIINFECTIVES AND ANTISEPTICS	1 (0.1)		1 (0.1)
IMMUNE SERA AND IMMUNOGLOBULINS	6 (0.8)	9 (1.2)	15 (1.0)
IMMUNOGLOBULINS, NORMAL HUMAN	1 (0.1)		1 (0.1)
SPECIFIC IMMUNOGLOBULINS	5 (0.7)	9 (1.2)	14 (1.0)
IMMUNOSUPPRESSANTS	1 (0.1)	2 (0.3)	3 (0.2)
OTHER IMMUNOSUPPRESSANTS		2 (0.3)	2 (0.1)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	1 (0.1)		1 (0.1)
LIPID MODIFYING AGENTS	1 (0.1)	3 (0.4)	4 (0.3)
HMG COA REDUCTASE INHIBITORS	1 (0.1)	2 (0.3)	3 (0.2)
OTHER LIPID MODIFYING AGENTS		1 (0.1)	1 (0.1)
MINERAL SUPPLEMENTS	18 (2.5)	51 (7.0)	69 (4.7)
CALCIUM	13 (1.8)	27 (3.7)	40 (2.7)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	1 (0.1)	10 (1.4)	11 (0.8)
MAGNESIUM	4 (0.6)	16 (2.2)	20 (1.4)
MULTIPLE ATC, 0	510 (70.2)	633 (86.7)	1143 (78.4)
MULTIPLE ATC, 0	510 (70.2)	633 (86.7)	1143 (78.4)
NASAL PREPARATIONS		1 (0.1)	1 (0.1)
Not coded		1 (0.1)	1 (0.1)
OPHTHALMOLOGICALS	3 (0.4)	6 (0.8)	9 (0.6)
BETA BLOCKING AGENTS		1 (0.1)	1 (0.1)
OTHER OPHTHALMOLOGICALS	1 (0.1)	4 (0.5)	5 (0.3)
PROSTAGLANDIN ANALOGUES	2 (0.3)	1 (0.1)	3 (0.2)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)		1 (0.1)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)		1 (0.1)
OTHER DERMATOLOGICAL PREPARATIONS		1 (0.1)	1 (0.1)
OTHER DERMATOLOGICALS		1 (0.1)	1 (0.1)
OTHER GYNECOLOGICALS	20 (2.8)	25 (3.4)	45 (3.1)
ERGOT ALKALOIDS AND OXYTOCIN INCL. ANALOGUES, IN COMBINATION	3 (0.4)	3 (0.4)	6 (0.4)
OTHER GYNECOLOGICALS	6 (0.8)	7 (1.0)	13 (0.9)
PROSTAGLANDINS	12 (1.7)	17 (2.3)	29 (2.0)
OTHER NERVOUS SYSTEM DRUGS		4 (0.5)	4 (0.3)
ANTIVERTIGO PREPARATIONS		1 (0.1)	1 (0.1)
DRUGS USED IN NICOTINE DEPENDENCE		3 (0.4)	3 (0.2)
OTOLOGICALS		1 (0.1)	1 (0.1)
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION		1 (0.1)	1 (0.1)
PANCREATIC HORMONES	2 (0.3)	4 (0.5)	6 (0.4)
GLYCOGENOLYTIC HORMONES	2 (0.3)	4 (0.5)	6 (0.4)
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES	26 (3.6)	28 (3.8)	54 (3.7)
ACTH		1 (0.1)	1 (0.1)
OXYTOCIN AND ANALOGUES	26 (3.6)	27 (3.7)	53 (3.6)
PSYCHOANALEPTICS	8 (1.1)	12 (1.6)	20 (1.4)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
CENTRALLY ACTING SYMPATHOMIMETICS		1 (0.1)	1 (0.1)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS		1 (0.1)	1 (0.1)
OTHER ANTIDEPRESSANTS		1 (0.1)	1 (0.1)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	8 (1.1)	9 (1.2)	17 (1.2)
PSYCHOLEPTICS	7 (1.0)	4 (0.5)	11 (0.8)
BENZODIAZEPINE DERIVATIVES	6 (0.8)	2 (0.3)	8 (0.5)
BENZODIAZEPINE RELATED DRUGS	1 (0.1)	2 (0.3)	3 (0.2)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	10 (1.4)	10 (1.4)	20 (1.4)
GONADOTROPINS	1 (0.1)		1 (0.1)
OVULATION STIMULANTS, SYNTHETIC	1 (0.1)	1 (0.1)	2 (0.1)
PREGNADIEN DERIVATIVES	6 (0.8)	4 (0.5)	10 (0.7)
PREGNEN (4) DERIVATIVES	1 (0.1)		1 (0.1)
PROGESTERONE RECEPTOR MODULATORS	2 (0.3)	3 (0.4)	5 (0.3)
PROGESTOGENS AND ESTROGENS, SEQUENTIAL PREPARATIONS		2 (0.3)	2 (0.1)
STOMATOLOGICAL PREPARATIONS		1 (0.1)	1 (0.1)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT		1 (0.1)	1 (0.1)
THROAT PREPARATIONS		1 (0.1)	1 (0.1)
ANTISEPTICS		1 (0.1)	1 (0.1)
THYROID THERAPY	159 (21.9)	197 (27.0)	356 (24.4)
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	2 (0.3)	1 (0.1)	3 (0.2)
THIOURACILS	4 (0.6)	2 (0.3)	6 (0.4)
THYROID HORMONES	153 (21.0)	194 (26.6)	347 (23.8)
TONICS	3 (0.4)	9 (1.2)	12 (0.8)
Not coded	3 (0.4)	9 (1.2)	12 (0.8)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE		1 (0.1)	1 (0.1)
Not coded		1 (0.1)	1 (0.1)
UROLOGICALS	1 (0.1)		1 (0.1)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	1 (0.1)		1 (0.1)
VACCINES	5 (0.7)	6 (0.8)	11 (0.8)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
BACTERIAL AND VIRAL VACCINES, COMBINED	2 (0.3)	2 (0.3)	4 (0.3)
INFLUENZA VACCINES	3 (0.4)	4 (0.5)	7 (0.5)
PERTUSSIS VACCINES	1 (0.1)		1 (0.1)
TETANUS VACCINES		1 (0.1)	1 (0.1)
VASOPROTECTIVES	1 (0.1)	1 (0.1)	2 (0.1)
BIOFLAVONOIDS	1 (0.1)	1 (0.1)	2 (0.1)
VITAMINS	85 (11.7)	142 (19.5)	227 (15.6)
MULTIVITAMINS WITH MINERALS	18 (2.5)	34 (4.7)	52 (3.6)
MULTIVITAMINS, OTHER COMBINATIONS	4 (0.6)	17 (2.3)	21 (1.4)
VITAMIN B-COMPLEX WITH VITAMIN C	2 (0.3)	1 (0.1)	3 (0.2)
VITAMIN B-COMPLEX, OTHER COMBINATIONS	1 (0.1)		1 (0.1)
VITAMIN B-COMPLEX, PLAIN	2 (0.3)	11 (1.5)	13 (0.9)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12		1 (0.1)	1 (0.1)
VITAMIN B1, PLAIN	2 (0.3)	2 (0.3)	4 (0.3)
VITAMIN D AND ANALOGUES	41 (5.6)	63 (8.6)	104 (7.1)
VITAMINS WITH MINERALS	7 (1.0)	11 (1.5)	18 (1.2)
VITAMINS, OTHER COMBINATIONS	10 (1.4)	10 (1.4)	20 (1.4)
Not coded	2 (0.3)	6 (0.8)	8 (0.5)
During first trimester, N (%)			
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	2 (0.3)	4 (0.5)	6 (0.4)
ACE INHIBITORS AND DIURETICS		1 (0.1)	1 (0.1)
ACE INHIBITORS, PLAIN	2 (0.3)	3 (0.4)	5 (0.3)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN		1 (0.1)	1 (0.1)
ANALGESICS	8 (1.1)	18 (2.5)	26 (1.8)
ANILIDES	6 (0.8)	17 (2.3)	23 (1.6)
NATURAL OPIUM ALKALOIDS		2 (0.3)	2 (0.1)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS		1 (0.1)	1 (0.1)
OTHER OPIOIDS	1 (0.1)	1 (0.1)	2 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
PHENYLPIPERIDINE DERIVATIVES	1 (0.1)		1 (0.1)
PYRAZOLONES		1 (0.1)	1 (0.1)
ANTI-ACNE PREPARATIONS		1 (0.1)	1 (0.1)
ANTIINFECTIVES FOR TREATMENT OF ACNE		1 (0.1)	1 (0.1)
ANTIANEMIC PREPARATIONS	37 (5.1)	66 (9.0)	103 (7.1)
FOLIC ACID AND DERIVATIVES	3 (0.4)	8 (1.1)	11 (0.8)
IRON BIVALENT, ORAL PREPARATIONS	13 (1.8)	14 (1.9)	27 (1.9)
IRON IN COMBINATION WITH FOLIC ACID	5 (0.7)	2 (0.3)	7 (0.5)
IRON IN OTHER COMBINATIONS	2 (0.3)	5 (0.7)	7 (0.5)
IRON TRIVALENT, ORAL PREPARATIONS		3 (0.4)	3 (0.2)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	14 (1.9)	37 (5.1)	51 (3.5)
Not coded		4 (0.5)	4 (0.3)
ANTIBACTERIALS FOR SYSTEMIC USE	9 (1.2)	21 (2.9)	30 (2.1)
BETA-LACTAMASE RESISTANT PENICILLINS	1 (0.1)		1 (0.1)
BETA-LACTAMASE SENSITIVE PENICILLINS		3 (0.4)	3 (0.2)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS		4 (0.5)	4 (0.3)
FIRST-GENERATION CEPHALOSPORINS	3 (0.4)	2 (0.3)	5 (0.3)
MONOBACTAMS		1 (0.1)	1 (0.1)
NITROFURAN DERIVATIVES	3 (0.4)	2 (0.3)	5 (0.3)
OTHER ANTIBACTERIALS	1 (0.1)	2 (0.3)	3 (0.2)
PENICILLINS WITH EXTENDED SPECTRUM	3 (0.4)	5 (0.7)	8 (0.5)
THIRD-GENERATION CEPHALOSPORINS	2 (0.3)	1 (0.1)	3 (0.2)
Not coded		1 (0.1)	1 (0.1)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE		1 (0.1)	1 (0.1)
ANTIVIRALS		1 (0.1)	1 (0.1)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	1 (0.1)	1 (0.1)	2 (0.1)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (0.1)	1 (0.1)	2 (0.1)
ANTIEMETICS AND ANTINAUSEANTS	5 (0.7)	11 (1.5)	16 (1.1)
OTHER ANTIEMETICS	3 (0.4)	5 (0.7)	8 (0.5)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
SEROTONIN (5HT3) ANTAGONISTS	3 (0.4)	6 (0.8)	9 (0.6)
ANTIEPILEPTICS	4 (0.6)	4 (0.5)	8 (0.5)
FATTY ACID DERIVATIVES	2 (0.3)	2 (0.3)	4 (0.3)
OTHER ANTIEPILEPTICS	2 (0.3)	3 (0.4)	5 (0.3)
ANTIFUNGALS FOR DERMATOLOGICAL USE		1 (0.1)	1 (0.1)
OTHER ANTIFUNGALS FOR TOPICAL USE		1 (0.1)	1 (0.1)
ANTIHEMORRHAGICS		1 (0.1)	1 (0.1)
VITAMIN K		1 (0.1)	1 (0.1)
ANTIHISTAMINES FOR SYSTEMIC USE	3 (0.4)	3 (0.4)	6 (0.4)
AMINOALKYL ETHERS		1 (0.1)	1 (0.1)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	2 (0.3)	1 (0.1)	3 (0.2)
PIPERAZINE DERIVATIVES	1 (0.1)	1 (0.1)	2 (0.1)
ANTIHYPERTENSIVES	26 (3.6)	27 (3.7)	53 (3.6)
METHYLDOPA	26 (3.6)	27 (3.7)	53 (3.6)
ANTIMYCOBACTERIALS		1 (0.1)	1 (0.1)
ANTIBIOTICS		1 (0.1)	1 (0.1)
OTHER DRUGS FOR TREATMENT OF TUBERCULOSIS		1 (0.1)	1 (0.1)
THIOCARBAMIDE DERIVATIVES		1 (0.1)	1 (0.1)
ANTIMYCOTICS FOR SYSTEMIC USE		1 (0.1)	1 (0.1)
TRIAZOLE DERIVATIVES		1 (0.1)	1 (0.1)
ANTINEOPLASTIC AGENTS		1 (0.1)	1 (0.1)
PURINE ANALOGUES		1 (0.1)	1 (0.1)
ANTITHROMBOTIC AGENTS	13 (1.8)	8 (1.1)	21 (1.4)
HEPARIN GROUP	13 (1.8)	8 (1.1)	21 (1.4)
ANTIVIRALS FOR SYSTEMIC USE	1 (0.1)	1 (0.1)	2 (0.1)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS		1 (0.1)	1 (0.1)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	1 (0.1)		1 (0.1)
OTHER ANTIVIRALS		1 (0.1)	1 (0.1)
BETA BLOCKING AGENTS	14 (1.9)	17 (2.3)	31 (2.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
ALPHA AND BETA BLOCKING AGENTS	9 (1.2)	14 (1.9)	23 (1.6)
BETA BLOCKING AGENTS, SELECTIVE	5 (0.7)	3 (0.4)	8 (0.5)
BILE AND LIVER THERAPY		3 (0.4)	3 (0.2)
BILE ACIDS AND DERIVATIVES		2 (0.3)	2 (0.1)
LIVER THERAPY		1 (0.1)	1 (0.1)
CALCIUM CHANNEL BLOCKERS	2 (0.3)	1 (0.1)	3 (0.2)
DIHYDROPYRIDINE DERIVATIVES	2 (0.3)	1 (0.1)	3 (0.2)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1)	2 (0.3)	3 (0.2)
CORTICOSTEROIDS, POTENT, COMBINATIONS WITH ANTIBIOTICS		1 (0.1)	1 (0.1)
CORTICOSTEROIDS, POTENT, OTHER COMBINATIONS	1 (0.1)		1 (0.1)
Not coded		1 (0.1)	1 (0.1)
DIURETICS	1 (0.1)	2 (0.3)	3 (0.2)
SULFONAMIDES, PLAIN	1 (0.1)	2 (0.3)	3 (0.2)
DRUGS FOR ACID RELATED DISORDERS	8 (1.1)	18 (2.5)	26 (1.8)
ANTACIDS, OTHER COMBINATIONS	1 (0.1)		1 (0.1)
H2-RECEPTOR ANTAGONISTS	3 (0.4)	4 (0.5)	7 (0.5)
PROTON PUMP INHIBITORS	5 (0.7)	14 (1.9)	19 (1.3)
DRUGS FOR CONSTIPATION	3 (0.4)	5 (0.7)	8 (0.5)
CONTACT LAXATIVES	1 (0.1)	1 (0.1)	2 (0.1)
OSMOTICALLY ACTING LAXATIVES	2 (0.3)	4 (0.5)	6 (0.4)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	3 (0.4)	3 (0.4)	6 (0.4)
PAPAVERINE AND DERIVATIVES	1 (0.1)		1 (0.1)
PROPULSIVES	2 (0.3)	3 (0.4)	5 (0.3)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	2 (0.3)	5 (0.7)	7 (0.5)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	1 (0.1)	4 (0.5)	5 (0.3)
LEUKOTRIENE RECEPTOR ANTAGONISTS	1 (0.1)	1 (0.1)	2 (0.1)
DRUGS USED IN DIABETES	727 (100)	730 (100)	1457 (100)
BIGUANIDES	41 (5.6)	32 (4.4)	73 (5.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	1 (0.1)		1 (0.1)
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES		1 (0.1)	1 (0.1)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	716 (98.5)	714 (97.8)	1430 (98.1)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING		96 (13.2)	96 (6.6)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	727 (100)	634 (86.8)	1361 (93.4)
Not coded	1 (0.1)		1 (0.1)
GENERAL NUTRIENTS	1 (0.1)	1 (0.1)	2 (0.1)
OTHER COMBINATIONS OF NUTRIENTS	1 (0.1)	1 (0.1)	2 (0.1)
IMMUNE SERA AND IMMUNOGLOBULINS		1 (0.1)	1 (0.1)
SPECIFIC IMMUNOGLOBULINS		1 (0.1)	1 (0.1)
IMMUNOSUPPRESSANTS	1 (0.1)	2 (0.3)	3 (0.2)
OTHER IMMUNOSUPPRESSANTS		2 (0.3)	2 (0.1)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	1 (0.1)		1 (0.1)
LIPID MODIFYING AGENTS	1 (0.1)	2 (0.3)	3 (0.2)
HMG COA REDUCTASE INHIBITORS	1 (0.1)	2 (0.3)	3 (0.2)
MINERAL SUPPLEMENTS	15 (2.1)	40 (5.5)	55 (3.8)
CALCIUM	13 (1.8)	26 (3.6)	39 (2.7)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	1 (0.1)	10 (1.4)	11 (0.8)
MAGNESIUM	1 (0.1)	6 (0.8)	7 (0.5)
MULTIPLE ATC, 0	495 (68.1)	613 (84.0)	1108 (76.0)
MULTIPLE ATC, 0	495 (68.1)	613 (84.0)	1108 (76.0)
OPHTHALMOLOGICALS	3 (0.4)	4 (0.5)	7 (0.5)
BETA BLOCKING AGENTS		1 (0.1)	1 (0.1)
OTHER OPHTHALMOLOGICALS	1 (0.1)	2 (0.3)	3 (0.2)
PROSTAGLANDIN ANALOGUES	2 (0.3)	1 (0.1)	3 (0.2)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)		1 (0.1)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)		1 (0.1)
OTHER GYNECOLOGICALS	2 (0.3)	1 (0.1)	3 (0.2)
OTHER GYNECOLOGICALS	1 (0.1)		1 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
PROSTAGLANDINS	1 (0.1)	1 (0.1)	2 (0.1)
OTHER NERVOUS SYSTEM DRUGS		2 (0.3)	2 (0.1)
ANTIVERTIGO PREPARATIONS		1 (0.1)	1 (0.1)
DRUGS USED IN NICOTINE DEPENDENCE		1 (0.1)	1 (0.1)
PANCREATIC HORMONES	2 (0.3)		2 (0.1)
GLYCOGENOLYTIC HORMONES	2 (0.3)		2 (0.1)
PSYCHOANALEPTICS	8 (1.1)	12 (1.6)	20 (1.4)
CENTRALLY ACTING SYMPATHOMIMETICS		1 (0.1)	1 (0.1)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS		1 (0.1)	1 (0.1)
OTHER ANTIDEPRESSANTS		1 (0.1)	1 (0.1)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	8 (1.1)	9 (1.2)	17 (1.2)
PSYCHOLEPTICS	2 (0.3)	1 (0.1)	3 (0.2)
BENZODIAZEPINE DERIVATIVES	2 (0.3)	1 (0.1)	3 (0.2)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	7 (1.0)	6 (0.8)	13 (0.9)
GONADOTROPINS	1 (0.1)		1 (0.1)
OVULATION STIMULANTS, SYNTHETIC	1 (0.1)	1 (0.1)	2 (0.1)
PREGNADIEN DERIVATIVES	5 (0.7)	3 (0.4)	8 (0.5)
PROGESTERONE RECEPTOR MODULATORS	1 (0.1)		1 (0.1)
PROGESTOGENS AND ESTROGENS, SEQUENTIAL PREPARATIONS		2 (0.3)	2 (0.1)
THYROID THERAPY	148 (20.4)	176 (24.1)	324 (22.2)
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	2 (0.3)	1 (0.1)	3 (0.2)
THIOURACILS	4 (0.6)	2 (0.3)	6 (0.4)
THYROID HORMONES	142 (19.5)	173 (23.7)	315 (21.6)
TONICS	3 (0.4)	7 (1.0)	10 (0.7)
Not coded	3 (0.4)	7 (1.0)	10 (0.7)
UROLOGICALS	1 (0.1)		1 (0.1)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	1 (0.1)		1 (0.1)
VACCINES		1 (0.1)	1 (0.1)
INFLUENZA VACCINES		1 (0.1)	1 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
VASOPROTECTIVES	1 (0.1)		1 (0.1)
BIOFLAVONOIDS	1 (0.1)		1 (0.1)
VITAMINS	76 (10.5)	114 (15.6)	190 (13.0)
MULTIVITAMINS WITH MINERALS	18 (2.5)	28 (3.8)	46 (3.2)
MULTIVITAMINS, OTHER COMBINATIONS	4 (0.6)	16 (2.2)	20 (1.4)
VITAMIN B-COMPLEX WITH VITAMIN C	1 (0.1)	1 (0.1)	2 (0.1)
VITAMIN B-COMPLEX, OTHER COMBINATIONS	1 (0.1)		1 (0.1)
VITAMIN B-COMPLEX, PLAIN	1 (0.1)	11 (1.5)	12 (0.8)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12		1 (0.1)	1 (0.1)
VITAMIN B1, PLAIN		1 (0.1)	1 (0.1)
VITAMIN D AND ANALOGUES	39 (5.4)	51 (7.0)	90 (6.2)
VITAMINS WITH MINERALS	6 (0.8)	9 (1.2)	15 (1.0)
VITAMINS, OTHER COMBINATIONS	8 (1.1)	3 (0.4)	11 (0.8)
Not coded	2 (0.3)	6 (0.8)	8 (0.5)
During second trimester, N (%)			
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	2 (0.3)	2 (0.3)	4 (0.3)
ACE INHIBITORS AND DIURETICS		1 (0.1)	1 (0.1)
ACE INHIBITORS, PLAIN	2 (0.3)	1 (0.1)	3 (0.2)
ANALGESICS	23 (3.2)	37 (5.1)	60 (4.1)
ANILIDES	20 (2.8)	31 (4.2)	51 (3.5)
NATURAL OPIUM ALKALOIDS	2 (0.3)	4 (0.5)	6 (0.4)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	2 (0.3)	4 (0.5)	6 (0.4)
OTHER OPIOIDS	1 (0.1)	1 (0.1)	2 (0.1)
PHENYLPIPERIDINE DERIVATIVES	1 (0.1)	3 (0.4)	4 (0.3)
PYRAZOLONES		2 (0.3)	2 (0.1)
SELECTIVE SEROTONIN (5HT1) AGONISTS		2 (0.3)	2 (0.1)
Not coded	1 (0.1)	2 (0.3)	3 (0.2)
ANESTHETICS	1 (0.1)	1 (0.1)	2 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
AMIDES	1 (0.1)	1 (0.1)	2 (0.1)
OPIOID ANESTHETICS	1 (0.1)		1 (0.1)
OTHER GENERAL ANESTHETICS	1 (0.1)		1 (0.1)
ANTI-ACNE PREPARATIONS		1 (0.1)	1 (0.1)
ANTIINFECTIVES FOR TREATMENT OF ACNE		1 (0.1)	1 (0.1)
ANTIANEMIC PREPARATIONS	42 (5.8)	81 (11.1)	123 (8.4)
FOLIC ACID AND DERIVATIVES	2 (0.3)	9 (1.2)	11 (0.8)
IRON BIVALENT, ORAL PREPARATIONS	21 (2.9)	33 (4.5)	54 (3.7)
IRON IN COMBINATION WITH FOLIC ACID	5 (0.7)	3 (0.4)	8 (0.5)
IRON IN OTHER COMBINATIONS	2 (0.3)	6 (0.8)	8 (0.5)
IRON TRIVALENT, ORAL PREPARATIONS		3 (0.4)	3 (0.2)
IRON, PARENTERAL PREPARATIONS	1 (0.1)		1 (0.1)
OTHER ANTIANEMIC PREPARATIONS		1 (0.1)	1 (0.1)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	13 (1.8)	36 (4.9)	49 (3.4)
Not coded		4 (0.5)	4 (0.3)
ANTIBACTERIALS FOR SYSTEMIC USE	29 (4.0)	42 (5.8)	71 (4.9)
BETA-LACTAMASE RESISTANT PENICILLINS	2 (0.3)	1 (0.1)	3 (0.2)
BETA-LACTAMASE SENSITIVE PENICILLINS		5 (0.7)	5 (0.3)
CARBAPENEMS		1 (0.1)	1 (0.1)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	6 (0.8)	9 (1.2)	15 (1.0)
FIRST-GENERATION CEPHALOSPORINS	3 (0.4)	4 (0.5)	7 (0.5)
MONOBACTAMS		1 (0.1)	1 (0.1)
NITROFURAN DERIVATIVES	5 (0.7)	7 (1.0)	12 (0.8)
OTHER ANTIBACTERIALS	2 (0.3)	5 (0.7)	7 (0.5)
PENICILLINS WITH EXTENDED SPECTRUM	14 (1.9)	11 (1.5)	25 (1.7)
SECOND-GENERATION CEPHALOSPORINS	2 (0.3)	1 (0.1)	3 (0.2)
THIRD-GENERATION CEPHALOSPORINS	2 (0.3)	2 (0.3)	4 (0.3)
TRIMETHOPRIM AND DERIVATIVES	1 (0.1)	1 (0.1)	2 (0.1)
Not coded		1 (0.1)	1 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE		1 (0.1)	1 (0.1)
ANTIVIRALS		1 (0.1)	1 (0.1)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	1 (0.1)	1 (0.1)	2 (0.1)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (0.1)	1 (0.1)	2 (0.1)
ANTIEMETICS AND ANTINAUSEANTS	11 (1.5)	21 (2.9)	32 (2.2)
OTHER ANTIEMETICS	1 (0.1)	5 (0.7)	6 (0.4)
SEROTONIN (5HT3) ANTAGONISTS	10 (1.4)	16 (2.2)	26 (1.8)
ANTIEPILEPTICS	4 (0.6)	4 (0.5)	8 (0.5)
FATTY ACID DERIVATIVES	2 (0.3)	2 (0.3)	4 (0.3)
OTHER ANTIEPILEPTICS	2 (0.3)	3 (0.4)	5 (0.3)
ANTIFUNGALS FOR DERMATOLOGICAL USE		1 (0.1)	1 (0.1)
OTHER ANTIFUNGALS FOR TOPICAL USE		1 (0.1)	1 (0.1)
ANTIHEMORRHAGICS		1 (0.1)	1 (0.1)
VITAMIN K		1 (0.1)	1 (0.1)
ANTIHISTAMINES FOR SYSTEMIC USE	3 (0.4)	6 (0.8)	9 (0.6)
AMINOALKYL ETHERS		1 (0.1)	1 (0.1)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	2 (0.3)	1 (0.1)	3 (0.2)
PIPERAZINE DERIVATIVES	1 (0.1)	1 (0.1)	2 (0.1)
SUBSTITUTED ALKYLAMINES		3 (0.4)	3 (0.2)
ANTIHYPERTENSIVES	25 (3.4)	36 (4.9)	61 (4.2)
METHYLDOPA	25 (3.4)	36 (4.9)	61 (4.2)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	1 (0.1)		1 (0.1)
FENAMATES	1 (0.1)		1 (0.1)
ANTIMYCOBACTERIALS		1 (0.1)	1 (0.1)
ANTIBIOTICS		1 (0.1)	1 (0.1)
OTHER DRUGS FOR TREATMENT OF TUBERCULOSIS		1 (0.1)	1 (0.1)
THIOCARBAMIDE DERIVATIVES		1 (0.1)	1 (0.1)
ANTIMYCOTICS FOR SYSTEMIC USE		1 (0.1)	1 (0.1)
TRIAZOLE DERIVATIVES		1 (0.1)	1 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
ANTINEOPLASTIC AGENTS		1 (0.1)	1 (0.1)
PURINE ANALOGUES		1 (0.1)	1 (0.1)
ANTITHROMBOTIC AGENTS	17 (2.3)	13 (1.8)	30 (2.1)
HEPARIN GROUP	17 (2.3)	13 (1.8)	30 (2.1)
ANTIVIRALS FOR SYSTEMIC USE	2 (0.3)	2 (0.3)	4 (0.3)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS	1 (0.1)	1 (0.1)	2 (0.1)
NEURAMINIDASE INHIBITORS		1 (0.1)	1 (0.1)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	1 (0.1)		1 (0.1)
OTHER ANTIVIRALS		1 (0.1)	1 (0.1)
BETA BLOCKING AGENTS	18 (2.5)	22 (3.0)	40 (2.7)
ALPHA AND BETA BLOCKING AGENTS	13 (1.8)	19 (2.6)	32 (2.2)
BETA BLOCKING AGENTS, SELECTIVE	5 (0.7)	3 (0.4)	8 (0.5)
BILE AND LIVER THERAPY	2 (0.3)	4 (0.5)	6 (0.4)
BILE ACIDS AND DERIVATIVES	2 (0.3)	3 (0.4)	5 (0.3)
LIVER THERAPY		1 (0.1)	1 (0.1)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	2 (0.3)	5 (0.7)	7 (0.5)
ELECTROLYTE SOLUTIONS		1 (0.1)	1 (0.1)
HYPERTONIC SOLUTIONS	1 (0.1)		1 (0.1)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	1 (0.1)	1 (0.1)	2 (0.1)
SOLUTIONS FOR PARENTERAL NUTRITION		4 (0.5)	4 (0.3)
CALCIUM CHANNEL BLOCKERS	3 (0.4)	1 (0.1)	4 (0.3)
DIHYDROPYRIDINE DERIVATIVES	3 (0.4)	1 (0.1)	4 (0.3)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1)		1 (0.1)
CORTICOSTEROIDS, POTENT, OTHER COMBINATIONS	1 (0.1)		1 (0.1)
COUGH AND COLD PREPARATIONS		2 (0.3)	2 (0.1)
EXPECTORANTS		1 (0.1)	1 (0.1)
OPIUM ALKALOIDS AND DERIVATIVES		1 (0.1)	1 (0.1)
DIURETICS	2 (0.3)	2 (0.3)	4 (0.3)
SULFONAMIDES, PLAIN	2 (0.3)	2 (0.3)	4 (0.3)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
DRUGS FOR ACID RELATED DISORDERS	12 (1.7)	29 (4.0)	41 (2.8)
ANTACIDS, OTHER COMBINATIONS	1 (0.1)		1 (0.1)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS		2 (0.3)	2 (0.1)
H2-RECEPTOR ANTAGONISTS	3 (0.4)	11 (1.5)	14 (1.0)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)		2 (0.3)	2 (0.1)
PROTON PUMP INHIBITORS	10 (1.4)	17 (2.3)	27 (1.9)
DRUGS FOR CONSTIPATION	4 (0.6)	6 (0.8)	10 (0.7)
CONTACT LAXATIVES	1 (0.1)		1 (0.1)
OSMOTICALLY ACTING LAXATIVES	3 (0.4)	5 (0.7)	8 (0.5)
OTHER DRUGS FOR CONSTIPATION		1 (0.1)	1 (0.1)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	10 (1.4)	12 (1.6)	22 (1.5)
PAPAVERINE AND DERIVATIVES	2 (0.3)	3 (0.4)	5 (0.3)
PROPULSIVES	8 (1.1)	9 (1.2)	17 (1.2)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	2 (0.3)	6 (0.8)	8 (0.5)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	1 (0.1)	5 (0.7)	6 (0.4)
LEUKOTRIENE RECEPTOR ANTAGONISTS	1 (0.1)	1 (0.1)	2 (0.1)
DRUGS USED IN DIABETES	687 (94.5)	694 (95.1)	1381 (94.8)
BIGUANIDES	35 (4.8)	33 (4.5)	68 (4.7)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	1 (0.1)		1 (0.1)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	680 (93.5)	686 (94.0)	1366 (93.8)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING		91 (12.5)	91 (6.2)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	687 (94.5)	603 (82.6)	1290 (88.5)
Not coded	1 (0.1)		1 (0.1)
GENERAL NUTRIENTS	1 (0.1)	2 (0.3)	3 (0.2)
OTHER COMBINATIONS OF NUTRIENTS	1 (0.1)	1 (0.1)	2 (0.1)
Not coded		1 (0.1)	1 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
IMMUNE SERA AND IMMUNOGLOBULINS	2 (0.3)	3 (0.4)	5 (0.3)
SPECIFIC IMMUNOGLOBULINS	2 (0.3)	3 (0.4)	5 (0.3)
IMMUNOSUPPRESSANTS	1 (0.1)	2 (0.3)	3 (0.2)
OTHER IMMUNOSUPPRESSANTS		2 (0.3)	2 (0.1)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	1 (0.1)		1 (0.1)
LIPID MODIFYING AGENTS	1 (0.1)	1 (0.1)	2 (0.1)
HMG COA REDUCTASE INHIBITORS	1 (0.1)	1 (0.1)	2 (0.1)
MINERAL SUPPLEMENTS	14 (1.9)	43 (5.9)	57 (3.9)
CALCIUM	12 (1.7)	26 (3.6)	38 (2.6)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	1 (0.1)	9 (1.2)	10 (0.7)
MAGNESIUM	1 (0.1)	10 (1.4)	11 (0.8)
MULTIPLE ATC, 0	470 (64.6)	596 (81.6)	1066 (73.2)
MULTIPLE ATC, 0	470 (64.6)	596 (81.6)	1066 (73.2)
NASAL PREPARATIONS		1 (0.1)	1 (0.1)
Not coded		1 (0.1)	1 (0.1)
OPHTHALMOLOGICALS	2 (0.3)	4 (0.5)	6 (0.4)
OTHER OPHTHALMOLOGICALS	1 (0.1)	3 (0.4)	4 (0.3)
PROSTAGLANDIN ANALOGUES	1 (0.1)	1 (0.1)	2 (0.1)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)		1 (0.1)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)		1 (0.1)
OTHER DERMATOLOGICAL PREPARATIONS		1 (0.1)	1 (0.1)
OTHER DERMATOLOGICALS		1 (0.1)	1 (0.1)
OTHER GYNECOLOGICALS	2 (0.3)	3 (0.4)	5 (0.3)
OTHER GYNECOLOGICALS	1 (0.1)	2 (0.3)	3 (0.2)
PROSTAGLANDINS	1 (0.1)	1 (0.1)	2 (0.1)
OTHER NERVOUS SYSTEM DRUGS		4 (0.5)	4 (0.3)
ANTIVERTIGO PREPARATIONS		1 (0.1)	1 (0.1)
DRUGS USED IN NICOTINE DEPENDENCE		3 (0.4)	3 (0.2)
PANCREATIC HORMONES	1 (0.1)	4 (0.5)	5 (0.3)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
GLYCOGENOLYTIC HORMONES	1 (0.1)	4 (0.5)	5 (0.3)
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES		2 (0.3)	2 (0.1)
ACTH		1 (0.1)	1 (0.1)
OXYTOCIN AND ANALOGUES		1 (0.1)	1 (0.1)
PSYCHOANALEPTICS	8 (1.1)	11 (1.5)	19 (1.3)
CENTRALLY ACTING SYMPATHOMIMETICS		1 (0.1)	1 (0.1)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS		1 (0.1)	1 (0.1)
OTHER ANTIDEPRESSANTS		1 (0.1)	1 (0.1)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	8 (1.1)	8 (1.1)	16 (1.1)
PSYCHOLEPTICS	2 (0.3)	3 (0.4)	5 (0.3)
BENZODIAZEPINE DERIVATIVES	1 (0.1)	2 (0.3)	3 (0.2)
BENZODIAZEPINE RELATED DRUGS	1 (0.1)	1 (0.1)	2 (0.1)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	7 (1.0)	7 (1.0)	14 (1.0)
PREGNADIEN DERIVATIVES	6 (0.8)	4 (0.5)	10 (0.7)
PREGNEN (4) DERIVATIVES	1 (0.1)		1 (0.1)
PROGESTERONE RECEPTOR MODULATORS		3 (0.4)	3 (0.2)
STOMATOLOGICAL PREPARATIONS		1 (0.1)	1 (0.1)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT		1 (0.1)	1 (0.1)
THROAT PREPARATIONS		1 (0.1)	1 (0.1)
ANTISEPTICS		1 (0.1)	1 (0.1)
THYROID THERAPY	148 (20.4)	184 (25.2)	332 (22.8)
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	2 (0.3)	1 (0.1)	3 (0.2)
THIOURACILS	4 (0.6)	2 (0.3)	6 (0.4)
THYROID HORMONES	142 (19.5)	181 (24.8)	323 (22.2)
TONICS	3 (0.4)	8 (1.1)	11 (0.8)
Not coded	3 (0.4)	8 (1.1)	11 (0.8)
UROLOGICALS	1 (0.1)		1 (0.1)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	1 (0.1)		1 (0.1)
VACCINES	3 (0.4)	2 (0.3)	5 (0.3)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
INFLUENZA VACCINES	3 (0.4)	2 (0.3)	5 (0.3)
VASOPROTECTIVES	1 (0.1)		1 (0.1)
BIOFLAVONOIDS	1 (0.1)		1 (0.1)
VITAMINS	81 (11.1)	134 (18.4)	215 (14.8)
MULTIVITAMINS WITH MINERALS	18 (2.5)	33 (4.5)	51 (3.5)
MULTIVITAMINS, OTHER COMBINATIONS	4 (0.6)	17 (2.3)	21 (1.4)
VITAMIN B-COMPLEX WITH VITAMIN C		1 (0.1)	1 (0.1)
VITAMIN B-COMPLEX, OTHER COMBINATIONS	1 (0.1)		1 (0.1)
VITAMIN B-COMPLEX, PLAIN	2 (0.3)	11 (1.5)	13 (0.9)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12		1 (0.1)	1 (0.1)
VITAMIN B1, PLAIN	2 (0.3)	1 (0.1)	3 (0.2)
VITAMIN D AND ANALOGUES	38 (5.2)	59 (8.1)	97 (6.7)
VITAMINS WITH MINERALS	7 (1.0)	10 (1.4)	17 (1.2)
VITAMINS, OTHER COMBINATIONS	10 (1.4)	9 (1.2)	19 (1.3)
Not coded	2 (0.3)	6 (0.8)	8 (0.5)
During third trimester, N (%)			
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	1 (0.1)	2 (0.3)	3 (0.2)
ACE INHIBITORS, PLAIN	1 (0.1)	2 (0.3)	3 (0.2)
ALL OTHER THERAPEUTIC PRODUCTS		1 (0.1)	1 (0.1)
ANTIDOTES		1 (0.1)	1 (0.1)
ANALGESICS	56 (7.7)	71 (9.7)	127 (8.7)
ANILIDES	45 (6.2)	60 (8.2)	105 (7.2)
NATURAL OPIUM ALKALOIDS	11 (1.5)	17 (2.3)	28 (1.9)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	10 (1.4)	8 (1.1)	18 (1.2)
OTHER ANALGESICS AND ANTIPYRETICS		1 (0.1)	1 (0.1)
OTHER OPIOIDS	3 (0.4)	3 (0.4)	6 (0.4)
PHENYLPIPERIDINE DERIVATIVES	1 (0.1)	1 (0.1)	2 (0.1)
PYRAZOLONES	4 (0.6)	5 (0.7)	9 (0.6)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
SELECTIVE SEROTONIN (5HT1) AGONISTS		1 (0.1)	1 (0.1)
Not coded	2 (0.3)	1 (0.1)	3 (0.2)
ANESTHETICS	16 (2.2)	18 (2.5)	34 (2.3)
AMIDES	3 (0.4)	6 (0.8)	9 (0.6)
OTHER GENERAL ANESTHETICS	5 (0.7)	2 (0.3)	7 (0.5)
Not coded	9 (1.2)	10 (1.4)	19 (1.3)
ANTI-ACNE PREPARATIONS		1 (0.1)	1 (0.1)
ANTIINFECTIVES FOR TREATMENT OF ACNE		1 (0.1)	1 (0.1)
ANTIANEMIC PREPARATIONS	51 (7.0)	85 (11.6)	136 (9.3)
FOLIC ACID AND DERIVATIVES	2 (0.3)	8 (1.1)	10 (0.7)
IRON BIVALENT, ORAL PREPARATIONS	31 (4.3)	44 (6.0)	75 (5.1)
IRON IN COMBINATION WITH FOLIC ACID	6 (0.8)	2 (0.3)	8 (0.5)
IRON IN OTHER COMBINATIONS	2 (0.3)	5 (0.7)	7 (0.5)
IRON TRIVALENT, ORAL PREPARATIONS		2 (0.3)	2 (0.1)
IRON, PARENTERAL PREPARATIONS	1 (0.1)	1 (0.1)	2 (0.1)
OTHER ANTIANEMIC PREPARATIONS		1 (0.1)	1 (0.1)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	11 (1.5)	27 (3.7)	38 (2.6)
Not coded		4 (0.5)	4 (0.3)
ANTIBACTERIALS FOR SYSTEMIC USE	40 (5.5)	54 (7.4)	94 (6.5)
BETA-LACTAMASE INHIBITORS		1 (0.1)	1 (0.1)
BETA-LACTAMASE RESISTANT PENICILLINS	1 (0.1)	2 (0.3)	3 (0.2)
BETA-LACTAMASE SENSITIVE PENICILLINS	2 (0.3)	3 (0.4)	5 (0.3)
CARBAPENEMS		2 (0.3)	2 (0.1)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	19 (2.6)	14 (1.9)	33 (2.3)
FIRST-GENERATION CEPHALOSPORINS	9 (1.2)	14 (1.9)	23 (1.6)
GLYCOPEPTIDE ANTIBACTERIALS		1 (0.1)	1 (0.1)
MONOBACTAMS		1 (0.1)	1 (0.1)
NITROFURAN DERIVATIVES	3 (0.4)	6 (0.8)	9 (0.6)
OTHER ANTIBACTERIALS	1 (0.1)	2 (0.3)	3 (0.2)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
PENICILLINS WITH EXTENDED SPECTRUM	7 (1.0)	14 (1.9)	21 (1.4)
SECOND-GENERATION CEPHALOSPORINS		1 (0.1)	1 (0.1)
THIRD-GENERATION CEPHALOSPORINS	1 (0.1)	3 (0.4)	4 (0.3)
TRIMETHOPRIM AND DERIVATIVES	2 (0.3)	1 (0.1)	3 (0.2)
Not coded		1 (0.1)	1 (0.1)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE		1 (0.1)	1 (0.1)
ANTIVIRALS		1 (0.1)	1 (0.1)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	1 (0.1)	1 (0.1)	2 (0.1)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (0.1)	1 (0.1)	2 (0.1)
ANTIEMETICS AND ANTINAUSEANTS	22 (3.0)	23 (3.2)	45 (3.1)
OTHER ANTIEMETICS	1 (0.1)	2 (0.3)	3 (0.2)
SEROTONIN (5HT3) ANTAGONISTS	21 (2.9)	21 (2.9)	42 (2.9)
ANTIEPILEPTICS	4 (0.6)	4 (0.5)	8 (0.5)
FATTY ACID DERIVATIVES	2 (0.3)	2 (0.3)	4 (0.3)
OTHER ANTIEPILEPTICS	2 (0.3)	3 (0.4)	5 (0.3)
ANTIFUNGALS FOR DERMATOLOGICAL USE		1 (0.1)	1 (0.1)
OTHER ANTIFUNGALS FOR TOPICAL USE		1 (0.1)	1 (0.1)
ANTIHISTAMINES FOR SYSTEMIC USE	5 (0.7)	5 (0.7)	10 (0.7)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	2 (0.3)	1 (0.1)	3 (0.2)
PIPERAZINE DERIVATIVES	1 (0.1)	1 (0.1)	2 (0.1)
SUBSTITUTED ALKYLAMINES	2 (0.3)	3 (0.4)	5 (0.3)
ANTIHYPERTENSIVES	37 (5.1)	73 (10.0)	110 (7.5)
ALPHA-ADRENORECEPTOR ANTAGONISTS		1 (0.1)	1 (0.1)
HYDRAZINOPHTHALAZINE DERIVATIVES	1 (0.1)	4 (0.5)	5 (0.3)
METHYLDOPA	36 (5.0)	71 (9.7)	107 (7.3)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	1 (0.1)		1 (0.1)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	1 (0.1)		1 (0.1)
ANTIMYCOBACTERIALS		1 (0.1)	1 (0.1)
ANTIBIOTICS		1 (0.1)	1 (0.1)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
OTHER DRUGS FOR TREATMENT OF TUBERCULOSIS		1 (0.1)	1 (0.1)
THIOCARBAMIDE DERIVATIVES		1 (0.1)	1 (0.1)
ANTIMYCOTICS FOR SYSTEMIC USE		1 (0.1)	1 (0.1)
TRIAZOLE DERIVATIVES		1 (0.1)	1 (0.1)
ANTINEOPLASTIC AGENTS		1 (0.1)	1 (0.1)
PURINE ANALOGUES		1 (0.1)	1 (0.1)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.		1 (0.1)	1 (0.1)
OTHER ANTIPRURITICS		1 (0.1)	1 (0.1)
ANTISEPTICS AND DISINFECTANTS	1 (0.1)		1 (0.1)
OTHER ANTISEPTICS AND DISINFECTANTS	1 (0.1)		1 (0.1)
ANTITHROMBOTIC AGENTS	37 (5.1)	40 (5.5)	77 (5.3)
HEPARIN GROUP	37 (5.1)	40 (5.5)	77 (5.3)
ANTIVIRALS FOR SYSTEMIC USE	2 (0.3)	3 (0.4)	5 (0.3)
ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS	1 (0.1)	1 (0.1)	2 (0.1)
NEURAMINIDASE INHIBITORS		2 (0.3)	2 (0.1)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	1 (0.1)		1 (0.1)
OTHER ANTIVIRALS		1 (0.1)	1 (0.1)
BETA BLOCKING AGENTS	41 (5.6)	66 (9.0)	107 (7.3)
ALPHA AND BETA BLOCKING AGENTS	36 (5.0)	61 (8.4)	97 (6.7)
BETA BLOCKING AGENTS, SELECTIVE	5 (0.7)	5 (0.7)	10 (0.7)
BILE AND LIVER THERAPY	2 (0.3)	11 (1.5)	13 (0.9)
BILE ACIDS AND DERIVATIVES	2 (0.3)	10 (1.4)	12 (0.8)
LIVER THERAPY		1 (0.1)	1 (0.1)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	16 (2.2)	21 (2.9)	37 (2.5)
BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS		1 (0.1)	1 (0.1)
HYPERTONIC SOLUTIONS	1 (0.1)	2 (0.3)	3 (0.2)
OTHER BLOOD PRODUCTS	1 (0.1)		1 (0.1)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	9 (1.2)	15 (2.1)	24 (1.6)
SOLUTIONS FOR PARENTERAL NUTRITION	5 (0.7)	9 (1.2)	14 (1.0)

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Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
Not coded	1 (0.1)	1 (0.1)	2 (0.1)
CALCIUM CHANNEL BLOCKERS	2 (0.3)	5 (0.7)	7 (0.5)
DIHYDROPYRIDINE DERIVATIVES	2 (0.3)	5 (0.7)	7 (0.5)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1)	1 (0.1)	2 (0.1)
CORTICOSTEROIDS, POTENT (GROUP III)		1 (0.1)	1 (0.1)
CORTICOSTEROIDS, POTENT, OTHER COMBINATIONS	1 (0.1)		1 (0.1)
COUGH AND COLD PREPARATIONS		1 (0.1)	1 (0.1)
EXPECTORANTS		1 (0.1)	1 (0.1)
DIURETICS	2 (0.3)	5 (0.7)	7 (0.5)
SULFONAMIDES, PLAIN	2 (0.3)	3 (0.4)	5 (0.3)
THIAZIDES, PLAIN		2 (0.3)	2 (0.1)
DRUGS FOR ACID RELATED DISORDERS	37 (5.1)	51 (7.0)	88 (6.0)
ANTACIDS, OTHER COMBINATIONS	1 (0.1)		1 (0.1)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS		2 (0.3)	2 (0.1)
H2-RECEPTOR ANTAGONISTS	28 (3.9)	35 (4.8)	63 (4.3)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	1 (0.1)	2 (0.3)	3 (0.2)
PROTON PUMP INHIBITORS	12 (1.7)	17 (2.3)	29 (2.0)
Not coded		1 (0.1)	1 (0.1)
DRUGS FOR CONSTIPATION	5 (0.7)	7 (1.0)	12 (0.8)
CONTACT LAXATIVES	1 (0.1)		1 (0.1)
OSMOTICALLY ACTING LAXATIVES	4 (0.6)	6 (0.8)	10 (0.7)
OTHER DRUGS FOR CONSTIPATION		1 (0.1)	1 (0.1)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	9 (1.2)	16 (2.2)	25 (1.7)
BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AMMONIUM COMPOUNDS		1 (0.1)	1 (0.1)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	1 (0.1)	4 (0.5)	5 (0.3)
PAPAVERINE AND DERIVATIVES	1 (0.1)	3 (0.4)	4 (0.3)
PROPULSIVES	7 (1.0)	8 (1.1)	15 (1.0)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	2 (0.3)	8 (1.1)	10 (0.7)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	1 (0.1)	6 (0.8)	7 (0.5)
LEUKOTRIENE RECEPTOR ANTAGONISTS	1 (0.1)	1 (0.1)	2 (0.1)
XANTHINES		1 (0.1)	1 (0.1)
DRUGS USED IN DIABETES	669 (92.0)	658 (90.1)	1327 (91.1)
BIGUANIDES	31 (4.3)	32 (4.4)	63 (4.3)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	1 (0.1)		1 (0.1)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	665 (91.5)	653 (89.5)	1318 (90.5)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING		87 (11.9)	87 (6.0)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	669 (92.0)	571 (78.2)	1240 (85.1)
Not coded	1 (0.1)		1 (0.1)
GENERAL NUTRIENTS	1 (0.1)	2 (0.3)	3 (0.2)
OTHER COMBINATIONS OF NUTRIENTS	1 (0.1)	1 (0.1)	2 (0.1)
Not coded		1 (0.1)	1 (0.1)
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	1 (0.1)	1 (0.1)	2 (0.1)
IMIDAZOLE DERIVATIVES		1 (0.1)	1 (0.1)
OTHER ANTIINFECTIVES AND ANTISEPTICS	1 (0.1)		1 (0.1)
IMMUNE SERA AND IMMUNOGLOBULINS	5 (0.7)	6 (0.8)	11 (0.8)
IMMUNOGLOBULINS, NORMAL HUMAN	1 (0.1)		1 (0.1)
SPECIFIC IMMUNOGLOBULINS	4 (0.6)	6 (0.8)	10 (0.7)
IMMUNOSUPPRESSANTS	1 (0.1)	2 (0.3)	3 (0.2)
OTHER IMMUNOSUPPRESSANTS		2 (0.3)	2 (0.1)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	1 (0.1)		1 (0.1)
LIPID MODIFYING AGENTS	1 (0.1)	2 (0.3)	3 (0.2)
HMG COA REDUCTASE INHIBITORS	1 (0.1)	1 (0.1)	2 (0.1)
OTHER LIPID MODIFYING AGENTS		1 (0.1)	1 (0.1)
MINERAL SUPPLEMENTS	16 (2.2)	49 (6.7)	65 (4.5)
CALCIUM	11 (1.5)	27 (3.7)	38 (2.6)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	1 (0.1)	9 (1.2)	10 (0.7)
MAGNESIUM	4 (0.6)	15 (2.1)	19 (1.3)
MULTIPLE ATC, 0	429 (59.0)	536 (73.4)	965 (66.2)
MULTIPLE ATC, 0	429 (59.0)	536 (73.4)	965 (66.2)
NASAL PREPARATIONS		1 (0.1)	1 (0.1)
Not coded		1 (0.1)	1 (0.1)
OPHTHALMOLOGICALS	2 (0.3)	4 (0.5)	6 (0.4)
OTHER OPHTHALMOLOGICALS	1 (0.1)	3 (0.4)	4 (0.3)
PROSTAGLANDIN ANALOGUES	1 (0.1)	1 (0.1)	2 (0.1)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)		1 (0.1)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	1 (0.1)		1 (0.1)
OTHER GYNECOLOGICALS	20 (2.8)	23 (3.2)	43 (3.0)
ERGOT ALKALOIDS AND OXYTOCIN INCL. ANALOGUES, IN COMBINATION	3 (0.4)	3 (0.4)	6 (0.4)
OTHER GYNECOLOGICALS	6 (0.8)	5 (0.7)	11 (0.8)
PROSTAGLANDINS	12 (1.7)	17 (2.3)	29 (2.0)
OTHER NERVOUS SYSTEM DRUGS		3 (0.4)	3 (0.2)
ANTIVERTIGO PREPARATIONS		1 (0.1)	1 (0.1)
DRUGS USED IN NICOTINE DEPENDENCE		2 (0.3)	2 (0.1)
OTOLOGICALS		1 (0.1)	1 (0.1)
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION		1 (0.1)	1 (0.1)
PANCREATIC HORMONES	1 (0.1)	1 (0.1)	2 (0.1)
GLYCOGENOLYTIC HORMONES	1 (0.1)	1 (0.1)	2 (0.1)
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES	26 (3.6)	26 (3.6)	52 (3.6)
OXYTOCIN AND ANALOGUES	26 (3.6)	26 (3.6)	52 (3.6)
PSYCHOANALEPTICS	8 (1.1)	10 (1.4)	18 (1.2)
CENTRALLY ACTING SYMPATHOMIMETICS		1 (0.1)	1 (0.1)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS		1 (0.1)	1 (0.1)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	8 (1.1)	8 (1.1)	16 (1.1)
PSYCHOLEPTICS	5 (0.7)	2 (0.3)	7 (0.5)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
BENZODIAZEPINE DERIVATIVES	5 (0.7)	1 (0.1)	6 (0.4)
BENZODIAZEPINE RELATED DRUGS		1 (0.1)	1 (0.1)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	7 (1.0)	2 (0.3)	9 (0.6)
PREGNADIEN DERIVATIVES	5 (0.7)	2 (0.3)	7 (0.5)
PREGNEN (4) DERIVATIVES	1 (0.1)		1 (0.1)
PROGESTERONE RECEPTOR MODULATORS	1 (0.1)		1 (0.1)
THROAT PREPARATIONS		1 (0.1)	1 (0.1)
ANTISEPTICS		1 (0.1)	1 (0.1)
THYROID THERAPY	147 (20.2)	178 (24.4)	325 (22.3)
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	2 (0.3)	1 (0.1)	3 (0.2)
THIOURACILS	4 (0.6)	1 (0.1)	5 (0.3)
THYROID HORMONES	141 (19.4)	176 (24.1)	317 (21.8)
TONICS	3 (0.4)	6 (0.8)	9 (0.6)
Not coded	3 (0.4)	6 (0.8)	9 (0.6)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE		1 (0.1)	1 (0.1)
Not coded		1 (0.1)	1 (0.1)
UROLOGICALS	1 (0.1)		1 (0.1)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	1 (0.1)		1 (0.1)
VACCINES	3 (0.4)	5 (0.7)	8 (0.5)
BACTERIAL AND VIRAL VACCINES, COMBINED	2 (0.3)	2 (0.3)	4 (0.3)
INFLUENZA VACCINES		2 (0.3)	2 (0.1)
PERTUSSIS VACCINES	1 (0.1)		1 (0.1)
TETANUS VACCINES		1 (0.1)	1 (0.1)
VASOPROTECTIVES	1 (0.1)	1 (0.1)	2 (0.1)
BIOFLAVONOIDS	1 (0.1)	1 (0.1)	2 (0.1)
VITAMINS	76 (10.5)	129 (17.7)	205 (14.1)
MULTIVITAMINS WITH MINERALS	17 (2.3)	31 (4.2)	48 (3.3)
MULTIVITAMINS, OTHER COMBINATIONS	3 (0.4)	15 (2.1)	18 (1.2)
VITAMIN B-COMPLEX WITH VITAMIN C	1 (0.1)	1 (0.1)	2 (0.1)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Glucose-lowering treatment and concomitant medication during pregnancy - summary - MOTHER

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
VITAMIN B-COMPLEX, OTHER COMBINATIONS	1 (0.1)		1 (0.1)
VITAMIN B-COMPLEX, PLAIN	2 (0.3)	11 (1.5)	13 (0.9)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12		1 (0.1)	1 (0.1)
VITAMIN B1, PLAIN	1 (0.1)		1 (0.1)
VITAMIN D AND ANALOGUES	35 (4.8)	57 (7.8)	92 (6.3)
VITAMINS WITH MINERALS	7 (1.0)	10 (1.4)	17 (1.2)
VITAMINS, OTHER COMBINATIONS	10 (1.4)	10 (1.4)	20 (1.4)
Not coded	2 (0.3)	6 (0.8)	8 (0.5)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

14.1.30 Medication use by the foetus/infant at any time during the study - summary – FAS_FOETUS

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Number of subjects	773	828	795	2396
Medication at any time during the study, N (%)				
ALL OTHER NON-THERAPEUTIC PRODUCTS		1 (0.1)		1 (0.0)
COSMETICS		1 (0.1)		1 (0.0)
ALL OTHER THERAPEUTIC PRODUCTS			1 (0.1)	1 (0.0)
OTHER THERAPEUTIC PRODUCTS			1 (0.1)	1 (0.0)
ANALGESICS	25 (3.2)	43 (5.2)	43 (5.4)	111 (4.6)
ANILIDES	24 (3.1)	40 (4.8)	43 (5.4)	107 (4.5)
MORPHINAN DERIVATIVES			1 (0.1)	1 (0.0)
NATURAL OPIUM ALKALOIDS	4 (0.5)	6 (0.7)	2 (0.3)	12 (0.5)
ANESTHETICS	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
OTHER GENERAL ANESTHETICS	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
ANTIANEMIC PREPARATIONS	1 (0.1)	3 (0.4)	6 (0.8)	10 (0.4)
IRON BIVALENT, ORAL PREPARATIONS		2 (0.2)	2 (0.3)	4 (0.2)
IRON TRIVALENT, ORAL PREPARATIONS	1 (0.1)		3 (0.4)	4 (0.2)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)		1 (0.1)	2 (0.3)	3 (0.1)
ANTIBACTERIALS FOR SYSTEMIC USE	25 (3.2)	52 (6.3)	50 (6.3)	127 (5.3)
AMPHENICOLS			1 (0.1)	1 (0.0)
BETA-LACTAMASE RESISTANT PENICILLINS	5 (0.6)	3 (0.4)	1 (0.1)	9 (0.4)
BETA-LACTAMASE SENSITIVE PENICILLINS	1 (0.1)	5 (0.6)	3 (0.4)	9 (0.4)
CARBAPENEMS		2 (0.2)	4 (0.5)	6 (0.3)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	6 (0.8)	14 (1.7)	14 (1.8)	34 (1.4)
COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES		3 (0.4)	5 (0.6)	8 (0.3)
FIRST-GENERATION CEPHALOSPORINS	1 (0.1)	2 (0.2)	2 (0.3)	5 (0.2)
FOURTH-GENERATION CEPHALOSPORINS		1 (0.1)		1 (0.0)
MACROLIDES			1 (0.1)	1 (0.0)
NITROFURAN DERIVATIVES	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
PENICILLINS WITH EXTENDED SPECTRUM	11 (1.4)	26 (3.1)	22 (2.8)	59 (2.5)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Medication use by the foetus/infant at any time during the study - summary – FAS_FOETUS

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
SECOND-GENERATION CEPHALOSPORINS	2 (0.3)	2 (0.2)		4 (0.2)
THIRD-GENERATION CEPHALOSPORINS	8 (1.0)	14 (1.7)	12 (1.5)	34 (1.4)
TRIMETHOPRIM AND DERIVATIVES	5 (0.6)	3 (0.4)	1 (0.1)	9 (0.4)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS		1 (0.1)	5 (0.6)	6 (0.3)
ANTIDIARRHEAL MICROORGANISMS		1 (0.1)	4 (0.5)	5 (0.2)
OTHER ANTIDIARRHEALS			1 (0.1)	1 (0.0)
ANTIEMETICS AND ANTINAUSEANTS	1 (0.1)	1 (0.1)		2 (0.1)
SEROTONIN (5HT3) ANTAGONISTS	1 (0.1)	1 (0.1)		2 (0.1)
ANTIEPILEPTICS	3 (0.4)	2 (0.2)	5 (0.6)	10 (0.4)
BARBITURATES AND DERIVATIVES	2 (0.3)	2 (0.2)	5 (0.6)	9 (0.4)
OTHER ANTIEPILEPTICS	1 (0.1)			1 (0.0)
ANTIFUNGALS FOR DERMATOLOGICAL USE	3 (0.4)	1 (0.1)	1 (0.1)	5 (0.2)
IMIDAZOLE AND TRIAZOLE DERIVATIVES	3 (0.4)	1 (0.1)	1 (0.1)	5 (0.2)
ANTIHEMORRHAGICS	15 (1.9)	17 (2.1)	18 (2.3)	50 (2.1)
BLOOD COAGULATION FACTORS			1 (0.1)	1 (0.0)
OTHER SYSTEMIC HEMOSTATICS			1 (0.1)	1 (0.0)
VITAMIN K	15 (1.9)	17 (2.1)	16 (2.0)	48 (2.0)
ANTIHISTAMINES FOR SYSTEMIC USE	2 (0.3)			2 (0.1)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	1 (0.1)			1 (0.0)
SUBSTITUTED ALKYLAMINES	1 (0.1)			1 (0.0)
ANTIHYPERTENSIVES		1 (0.1)		1 (0.0)
ANTIHYPERTENSIVES FOR PULMONARY ARTERIAL HYPERTENSION		1 (0.1)		1 (0.0)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	1 (0.1)			1 (0.0)
Not coded	1 (0.1)			1 (0.0)
ANTITHROMBOTIC AGENTS	1 (0.1)		2 (0.3)	3 (0.1)
ENZYMES			1 (0.1)	1 (0.0)
HEPARIN GROUP			1 (0.1)	1 (0.0)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	1 (0.1)			1 (0.0)
ANTIVIRALS FOR SYSTEMIC USE	3 (0.4)	1 (0.1)	1 (0.1)	5 (0.2)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Medication use by the foetus/infant at any time during the study - summary – FAS_FOETUS

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
NEURAMINIDASE INHIBITORS	2 (0.3)			2 (0.1)
NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS		1 (0.1)	1 (0.1)	2 (0.1)
OTHER ANTIVIRALS	1 (0.1)			1 (0.0)
BETA BLOCKING AGENTS			1 (0.1)	1 (0.0)
ALPHA AND BETA BLOCKING AGENTS			1 (0.1)	1 (0.0)
BILE AND LIVER THERAPY	1 (0.1)		1 (0.1)	2 (0.1)
BILE ACIDS AND DERIVATIVES	1 (0.1)		1 (0.1)	2 (0.1)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	13 (1.7)	14 (1.7)	13 (1.6)	40 (1.7)
ELECTROLYTE SOLUTIONS	1 (0.1)			1 (0.0)
HYPERTONIC SOLUTIONS			2 (0.3)	2 (0.1)
OTHER BLOOD PRODUCTS	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE		1 (0.1)		1 (0.0)
SOLUTIONS FOR PARENTERAL NUTRITION	12 (1.6)	12 (1.4)	10 (1.3)	34 (1.4)
Not coded		1 (0.1)		1 (0.0)
CARDIAC THERAPY	1 (0.1)	2 (0.2)	3 (0.4)	6 (0.3)
ADRENERGIC AND DOPAMINERGIC AGENTS	1 (0.1)	2 (0.2)	2 (0.3)	5 (0.2)
ANTIARRHYTHMICS, CLASS IC			1 (0.1)	1 (0.0)
PHOSPHODIESTERASE INHIBITORS			1 (0.1)	1 (0.0)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
CORTICOSTEROIDS, WEAK, COMBINATIONS WITH ANTIBIOTICS	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
COUGH AND COLD PREPARATIONS			2 (0.3)	2 (0.1)
MUCOLYTICS			1 (0.1)	1 (0.0)
OTHER COUGH SUPPRESSANTS			1 (0.1)	1 (0.0)
DIGESTIVES, INCL. ENZYMES	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
ENZYME PREPARATIONS	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
DIURETICS	5 (0.6)	5 (0.6)	3 (0.4)	13 (0.5)
ALDOSTERONE ANTAGONISTS	3 (0.4)	2 (0.2)		5 (0.2)
SULFONAMIDES, PLAIN	5 (0.6)	4 (0.5)	1 (0.1)	10 (0.4)
THIAZIDES, PLAIN		1 (0.1)	1 (0.1)	2 (0.1)

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Medication use by the foetus/infant at any time during the study - summary – FAS_FOETUS

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Not coded			1 (0.1)	1 (0.0)
DRUGS FOR ACID RELATED DISORDERS	9 (1.2)	18 (2.2)	13 (1.6)	40 (1.7)
H2-RECEPTOR ANTAGONISTS	2 (0.3)	5 (0.6)	5 (0.6)	12 (0.5)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	1 (0.1)	4 (0.5)	1 (0.1)	6 (0.3)
PROTON PUMP INHIBITORS	7 (0.9)	12 (1.4)	7 (0.9)	26 (1.1)
Not coded		1 (0.1)	2 (0.3)	3 (0.1)
DRUGS FOR CONSTIPATION	1 (0.1)	7 (0.8)	1 (0.1)	9 (0.4)
OSMOTICALLY ACTING LAXATIVES	1 (0.1)	7 (0.8)	1 (0.1)	9 (0.4)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS		5 (0.6)	1 (0.1)	6 (0.3)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS		5 (0.6)		5 (0.2)
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP			1 (0.1)	1 (0.0)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	3 (0.4)	5 (0.6)	6 (0.8)	14 (0.6)
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS	1 (0.1)	1 (0.1)	5 (0.6)	7 (0.3)
LEUKOTRIENE RECEPTOR ANTAGONISTS	2 (0.3)	3 (0.4)	1 (0.1)	6 (0.3)
XANTHINES		1 (0.1)	1 (0.1)	2 (0.1)
DRUGS USED IN DIABETES	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	1 (0.1)	1 (0.1)		2 (0.1)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING		1 (0.1)		1 (0.0)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	1 (0.1)			1 (0.0)
Not coded			1 (0.1)	1 (0.0)
EMOLLIENTS AND PROTECTIVES	1 (0.1)		2 (0.3)	3 (0.1)
OTHER EMOLLIENTS AND PROTECTIVES			1 (0.1)	1 (0.0)
SOFT PARAFFIN AND FAT PRODUCTS			1 (0.1)	1 (0.0)
ZINC PRODUCTS	1 (0.1)			1 (0.0)
Not coded			1 (0.1)	1 (0.0)
GENERAL NUTRIENTS	6 (0.8)	12 (1.4)	15 (1.9)	33 (1.4)
CARBOHYDRATES	1 (0.1)		2 (0.3)	3 (0.1)

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Medication use by the foetus/infant at any time during the study - summary – FAS_FOETUS

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
MILK SUBSTITUTES		2 (0.2)	6 (0.8)	8 (0.3)
Not coded	5 (0.6)	10 (1.2)	7 (0.9)	22 (0.9)
IMMUNE SERA AND IMMUNOGLOBULINS	2 (0.3)	1 (0.1)	4 (0.5)	7 (0.3)
IMMUNOGLOBULINS, NORMAL HUMAN	1 (0.1)		3 (0.4)	4 (0.2)
SPECIFIC IMMUNOGLOBULINS	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
MINERAL SUPPLEMENTS	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
CALCIUM	2 (0.3)	1 (0.1)		3 (0.1)
Not coded			1 (0.1)	1 (0.0)
MULTIPLE ATC, 0	148 (19.1)	199 (24.0)	194 (24.4)	541 (22.6)
MULTIPLE ATC, 0	148 (19.1)	199 (24.0)	194 (24.4)	541 (22.6)
MUSCLE RELAXANTS		2 (0.2)	1 (0.1)	3 (0.1)
CHOLINE DERIVATIVES		1 (0.1)	1 (0.1)	2 (0.1)
OTHER QUATERNARY AMMONIUM COMPOUNDS		1 (0.1)		1 (0.0)
NASAL PREPARATIONS			1 (0.1)	1 (0.0)
OTHER NASAL PREPARATIONS			1 (0.1)	1 (0.0)
OPHTHALMOLOGICALS		2 (0.2)	2 (0.3)	4 (0.2)
ANTICHOLINERGICS		1 (0.1)	1 (0.1)	2 (0.1)
ANTINEOVASCULARISATION AGENTS		1 (0.1)	1 (0.1)	2 (0.1)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS		1 (0.1)		1 (0.0)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS		1 (0.1)		1 (0.0)
OTHER DERMATOLOGICAL PREPARATIONS		1 (0.1)		1 (0.0)
OTHER DERMATOLOGICALS		1 (0.1)		1 (0.0)
OTHER RESPIRATORY SYSTEM PRODUCTS		3 (0.4)	3 (0.4)	6 (0.3)
LUNG SURFACTANTS		3 (0.4)	3 (0.4)	6 (0.3)
PANCREATIC HORMONES	1 (0.1)		2 (0.3)	3 (0.1)
GLYCOGENOLYTIC HORMONES	1 (0.1)		2 (0.3)	3 (0.1)
PERIPHERAL VASODILATORS	1 (0.1)		4 (0.5)	5 (0.2)
PURINE DERIVATIVES	1 (0.1)		4 (0.5)	5 (0.2)
PSYCHOLEPTICS	2 (0.3)	1 (0.1)	2 (0.3)	5 (0.2)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Medication use by the foetus/infant at any time during the study - summary – FAS_FOETUS

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
ALDEHYDES AND DERIVATIVES	1 (0.1)	1 (0.1)		2 (0.1)
BENZODIAZEPINE DERIVATIVES	1 (0.1)		1 (0.1)	2 (0.1)
OTHER ANTIPSYCHOTICS			1 (0.1)	1 (0.0)
THYROID THERAPY		1 (0.1)	1 (0.1)	2 (0.1)
THYROID HORMONES		1 (0.1)	1 (0.1)	2 (0.1)
TONICS		4 (0.5)	14 (1.8)	18 (0.8)
Not coded		4 (0.5)	14 (1.8)	18 (0.8)
UROLOGICALS		1 (0.1)		1 (0.0)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE		1 (0.1)		1 (0.0)
VACCINES	3 (0.4)		1 (0.1)	4 (0.2)
HEPATITIS VACCINES	1 (0.1)		1 (0.1)	2 (0.1)
TETANUS VACCINES	1 (0.1)			1 (0.0)
Not coded	1 (0.1)			1 (0.0)
VITAMINS	10 (1.3)	25 (3.0)	51 (6.4)	86 (3.6)
COMBINATIONS OF VITAMINS	1 (0.1)		9 (1.1)	10 (0.4)
MULTIVITAMINS, PLAIN	3 (0.4)	2 (0.2)	2 (0.3)	7 (0.3)
VITAMIN D AND ANALOGUES	7 (0.9)	23 (2.8)	41 (5.2)	71 (3.0)
Not coded			2 (0.3)	2 (0.1)
Not coded	3 (0.4)	3 (0.4)	1 (0.1)	7 (0.3)
Not coded	3 (0.4)	3 (0.4)	1 (0.1)	7 (0.3)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

14.1.31 Medication use by the foetus/infant at any time during the study - summary – FOETUS

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
Number of subjects	741	740	1481
Medication at any time during the study, N (%)			
ANALGESICS	23 (3.1)	34 (4.6)	57 (3.8)
ANILIDES	22 (3.0)	31 (4.2)	53 (3.6)
NATURAL OPIUM ALKALOIDS	4 (0.5)	5 (0.7)	9 (0.6)
ANESTHETICS	1 (0.1)	1 (0.1)	2 (0.1)
OTHER GENERAL ANESTHETICS	1 (0.1)	1 (0.1)	2 (0.1)
ANTIANEMIC PREPARATIONS	1 (0.1)	3 (0.4)	4 (0.3)
IRON BIVALENT, ORAL PREPARATIONS		2 (0.3)	2 (0.1)
IRON TRIVALENT, ORAL PREPARATIONS	1 (0.1)		1 (0.1)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)		1 (0.1)	1 (0.1)
ANTIBACTERIALS FOR SYSTEMIC USE	25 (3.4)	45 (6.1)	70 (4.7)
BETA-LACTAMASE RESISTANT PENICILLINS	5 (0.7)	3 (0.4)	8 (0.5)
BETA-LACTAMASE SENSITIVE PENICILLINS	1 (0.1)	4 (0.5)	5 (0.3)
CARBAPENEMS		2 (0.3)	2 (0.1)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	6 (0.8)	13 (1.8)	19 (1.3)
COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES		3 (0.4)	3 (0.2)
FIRST-GENERATION CEPHALOSPORINS	1 (0.1)	2 (0.3)	3 (0.2)
FOURTH-GENERATION CEPHALOSPORINS		1 (0.1)	1 (0.1)
NITROFURAN DERIVATIVES	1 (0.1)	2 (0.3)	3 (0.2)
PENICILLINS WITH EXTENDED SPECTRUM	11 (1.5)	22 (3.0)	33 (2.2)
SECOND-GENERATION CEPHALOSPORINS	2 (0.3)	1 (0.1)	3 (0.2)
THIRD-GENERATION CEPHALOSPORINS	8 (1.1)	11 (1.5)	19 (1.3)
TRIMETHOPRIM AND DERIVATIVES	5 (0.7)	3 (0.4)	8 (0.5)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS		1 (0.1)	1 (0.1)
ANTIDIARRHEAL MICROORGANISMS		1 (0.1)	1 (0.1)
ANTIEMETICS AND ANTINAUSEANTS	1 (0.1)		1 (0.1)
SEROTONIN (5HT3) ANTAGONISTS	1 (0.1)		1 (0.1)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Medication use by the foetus/infant at any time during the study - summary – FOETUS

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
ANTIEPILEPTICS	3 (0.4)	2 (0.3)	5 (0.3)
BARBITURATES AND DERIVATIVES	2 (0.3)	2 (0.3)	4 (0.3)
OTHER ANTIEPILEPTICS	1 (0.1)		1 (0.1)
ANTIFUNGALS FOR DERMATOLOGICAL USE	3 (0.4)	1 (0.1)	4 (0.3)
IMIDAZOLE AND TRIAZOLE DERIVATIVES	3 (0.4)	1 (0.1)	4 (0.3)
ANTIHEMORRHAGICS	15 (2.0)	15 (2.0)	30 (2.0)
VITAMIN K	15 (2.0)	15 (2.0)	30 (2.0)
ANTIHISTAMINES FOR SYSTEMIC USE	2 (0.3)		2 (0.1)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	1 (0.1)		1 (0.1)
SUBSTITUTED ALKYLAMINES	1 (0.1)		1 (0.1)
ANTIHYPERTENSIVES		1 (0.1)	1 (0.1)
ANTIHYPERTENSIVES FOR PULMONARY ARTERIAL HYPERTENSION		1 (0.1)	1 (0.1)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	1 (0.1)		1 (0.1)
Not coded	1 (0.1)		1 (0.1)
ANTITHROMBOTIC AGENTS	1 (0.1)		1 (0.1)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	1 (0.1)		1 (0.1)
ANTIVIRALS FOR SYSTEMIC USE	3 (0.4)	1 (0.1)	4 (0.3)
NEURAMINIDASE INHIBITORS	2 (0.3)		2 (0.1)
NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS		1 (0.1)	1 (0.1)
OTHER ANTIVIRALS	1 (0.1)		1 (0.1)
BILE AND LIVER THERAPY	1 (0.1)		1 (0.1)
BILE ACIDS AND DERIVATIVES	1 (0.1)		1 (0.1)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	13 (1.8)	12 (1.6)	25 (1.7)
ELECTROLYTE SOLUTIONS	1 (0.1)		1 (0.1)
OTHER BLOOD PRODUCTS	1 (0.1)	1 (0.1)	2 (0.1)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE		1 (0.1)	1 (0.1)
SOLUTIONS FOR PARENTERAL NUTRITION	12 (1.6)	10 (1.4)	22 (1.5)
Not coded		1 (0.1)	1 (0.1)
CARDIAC THERAPY	1 (0.1)	1 (0.1)	2 (0.1)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Medication use by the foetus/infant at any time during the study - summary – FOETUS

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
ADRENERGIC AND DOPAMINERGIC AGENTS	1 (0.1)	1 (0.1)	2 (0.1)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.1)	1 (0.1)	2 (0.1)
CORTICOSTEROIDS, WEAK, COMBINATIONS WITH ANTIBIOTICS	1 (0.1)	1 (0.1)	2 (0.1)
DIGESTIVES, INCL. ENZYMES	2 (0.3)	1 (0.1)	3 (0.2)
ENZYME PREPARATIONS	2 (0.3)	1 (0.1)	3 (0.2)
DIURETICS	5 (0.7)	4 (0.5)	9 (0.6)
ALDOSTERONE ANTAGONISTS	3 (0.4)	1 (0.1)	4 (0.3)
SULFONAMIDES, PLAIN	5 (0.7)	3 (0.4)	8 (0.5)
THIAZIDES, PLAIN		1 (0.1)	1 (0.1)
DRUGS FOR ACID RELATED DISORDERS	9 (1.2)	16 (2.2)	25 (1.7)
H2-RECEPTOR ANTAGONISTS	2 (0.3)	5 (0.7)	7 (0.5)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	1 (0.1)	4 (0.5)	5 (0.3)
PROTON PUMP INHIBITORS	7 (0.9)	10 (1.4)	17 (1.1)
Not coded		1 (0.1)	1 (0.1)
DRUGS FOR CONSTIPATION	1 (0.1)	7 (0.9)	8 (0.5)
OSMOTICALLY ACTING LAXATIVES	1 (0.1)	7 (0.9)	8 (0.5)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS		4 (0.5)	4 (0.3)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS		4 (0.5)	4 (0.3)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	3 (0.4)	4 (0.5)	7 (0.5)
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS	1 (0.1)	1 (0.1)	2 (0.1)
LEUKOTRIENE RECEPTOR ANTAGONISTS	2 (0.3)	2 (0.3)	4 (0.3)
XANTHINES		1 (0.1)	1 (0.1)
DRUGS USED IN DIABETES	1 (0.1)	1 (0.1)	2 (0.1)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	1 (0.1)	1 (0.1)	2 (0.1)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING		1 (0.1)	1 (0.1)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	1 (0.1)		1 (0.1)
EMOLLIENTS AND PROTECTIVES	1 (0.1)		1 (0.1)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Medication use by the foetus/infant at any time during the study - summary – FOETUS

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
ZINC PRODUCTS	1 (0.1)		1 (0.1)
GENERAL NUTRIENTS	5 (0.7)	10 (1.4)	15 (1.0)
MILK SUBSTITUTES		1 (0.1)	1 (0.1)
Not coded	5 (0.7)	9 (1.2)	14 (0.9)
IMMUNE SERA AND IMMUNOGLOBULINS	2 (0.3)	1 (0.1)	3 (0.2)
IMMUNOGLOBULINS, NORMAL HUMAN	1 (0.1)		1 (0.1)
SPECIFIC IMMUNOGLOBULINS	1 (0.1)	1 (0.1)	2 (0.1)
MINERAL SUPPLEMENTS	2 (0.3)	1 (0.1)	3 (0.2)
CALCIUM	2 (0.3)	1 (0.1)	3 (0.2)
MULTIPLE ATC, 0	139 (18.8)	168 (22.7)	307 (20.7)
MULTIPLE ATC, 0	139 (18.8)	168 (22.7)	307 (20.7)
MUSCLE RELAXANTS		2 (0.3)	2 (0.1)
CHOLINE DERIVATIVES		1 (0.1)	1 (0.1)
OTHER QUATERNARY AMMONIUM COMPOUNDS		1 (0.1)	1 (0.1)
OPHTHALMOLOGICALS		2 (0.3)	2 (0.1)
ANTICHOLINERGICS		1 (0.1)	1 (0.1)
ANTINEOVASCULARISATION AGENTS		1 (0.1)	1 (0.1)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS		1 (0.1)	1 (0.1)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS		1 (0.1)	1 (0.1)
OTHER DERMATOLOGICAL PREPARATIONS		1 (0.1)	1 (0.1)
OTHER DERMATOLOGICALS		1 (0.1)	1 (0.1)
OTHER RESPIRATORY SYSTEM PRODUCTS		3 (0.4)	3 (0.2)
LUNG SURFACTANTS		3 (0.4)	3 (0.2)
PANCREATIC HORMONES	1 (0.1)		1 (0.1)
GLYCOGENOLYTIC HORMONES	1 (0.1)		1 (0.1)
PERIPHERAL VASODILATORS	1 (0.1)		1 (0.1)
PURINE DERIVATIVES	1 (0.1)		1 (0.1)
PSYCHOLEPTICS	2 (0.3)	1 (0.1)	3 (0.2)
ALDEHYDES AND DERIVATIVES	1 (0.1)	1 (0.1)	2 (0.1)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

Medication use by the foetus/infant at any time during the study - summary – FOETUS

ATC2 ATC4	Insulin detemir N (%)	Other basal insulin N (%)	Total N (%)
BENZODIAZEPINE DERIVATIVES	1 (0.1)		1 (0.1)
THYROID THERAPY		1 (0.1)	1 (0.1)
THYROID HORMONES		1 (0.1)	1 (0.1)
TONICS		1 (0.1)	1 (0.1)
Not coded		1 (0.1)	1 (0.1)
UROLOGICALS		1 (0.1)	1 (0.1)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE		1 (0.1)	1 (0.1)
VACCINES	3 (0.4)		3 (0.2)
HEPATITIS VACCINES	1 (0.1)		1 (0.1)
TETANUS VACCINES	1 (0.1)		1 (0.1)
Not coded	1 (0.1)		1 (0.1)
VITAMINS	7 (0.9)	12 (1.6)	19 (1.3)
MULTIVITAMINS, PLAIN	3 (0.4)	2 (0.3)	5 (0.3)
VITAMIN D AND ANALOGUES	4 (0.5)	10 (1.4)	14 (0.9)
Not coded	2 (0.3)	3 (0.4)	5 (0.3)
Not coded	2 (0.3)	3 (0.4)	5 (0.3)

N: Number of patients, %: Percentage of patients, ATC: Anatomical Therapeutic Chemical

14.1.32 Pregnancy outcomes not resulting in major malformations, perinatal death or neonatal death among foetus of women treated with basal insulin detemir compared to other basal insulins - summary – Primary analysis set

	N	Events	Risk/Odds		95% CI	P-value
N = 1330						
Before propensity score matching						
Insulin detemir	667	647	0.97/32.35			
Other basal insulin	663	633	0.95/21.10			
Insulin detemir vs Other basal insulin						
Risk difference				0.015	[-0.01, 0.04]	0.1518
Odds ratio				1.533	[0.86, 2.73]	
N = 770						
After propensity score matching						
Insulin detemir	385	368	0.96/21.65			
Other basal insulin	385	369	0.96/23.06			
Insulin detemir vs Other basal insulin						
Risk difference				-0.003	[-0.03, 0.03]	0.8575
Odds ratio				0.939	[0.47, 1.89]	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher’s exact test (crude analysis) and McNemar’s test for correlated binomial proportions (propensity score matched analysis).

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14.1.33 Baseline characteristics by basal insulin treatment group at enrolment before propensity score matching - PRIMARY analysis set

	Before propensity score matching(N =1360)		
	Insulin Detemir (N =684)	Other Basal Insulin (N =676)	P-value
Age (years)			
N	684	676	0.1701
Mean (SD)	30.91 (4.98)	30.63 (5.33)	
Median	31.00	30.00	
2.5; 97.5 Percentiles	21.00 ; 40.00	21.00 ; 41.00	
Min ; Max	18.00 ; 44.00	17.00 ; 47.00	
Gestational age (weeks)			
N	682	671	0.6332
Mean (SD)	8.87 (2.43)	8.97 (2.54)	
Median	9.00	9.00	
2.5; 97.5 Percentiles	5.00 ; 14.00	5.00 ; 15.00	
Min ; Max	4.00 ; 16.00	3.00 ; 16.00	
Duration of DM (years)			
N	681	670	0.2973
Mean (SD)	13.11 (8.03)	13.70 (8.56)	
Median	12.00	13.00	
2.5; 97.5 Percentiles	2.00 ; 29.00	2.00 ; 30.00	
Min ; Max	1.00 ; 35.00	1.00 ; 38.00	
HbA1C (%)			
N	651	642	0.0195
Mean (SD)	6.90 (1.21)	7.09 (1.32)	
Median	6.70	6.80	
2.5; 97.5 Percentiles	5.20 ; 9.90	5.36 ; 10.20	
Min ; Max	4.40 ; 13.90	4.71 ; 14.50	
Body Mass Index (kg/m2)			
N	661	650	0.0001
Mean (SD)	25.76 (5.74)	26.73 (5.76)	
Median	24.30	25.40	
2.5; 97.5 Percentiles	18.60 ; 40.80	19.30 ; 42.20	
Min ; Max	16.30 ; 52.50	17.30 ; 49.00	
Country, N (%)			
N	684	676	<0.001
Croatia	222 (32.5)	40 (5.9)	
Denmark	124 (18.1)	254 (37.6)	
Finland	55 (8.0)	46 (6.8)	
France	8 (1.2)	12 (1.8)	
Germany	4 (0.6)	7 (1.0)	
Greece	3 (0.4)	7 (1.0)	
Ireland	29 (4.2)	24 (3.6)	
Israel	48 (7.0)	7 (1.0)	
Italy	15 (2.2)	21 (3.1)	
Malaysia	3 (0.4)	13 (1.9)	
Netherlands	12 (1.8)	6 (0.9)	

Differences between treatment groups are tested using chi-square test for categorical variables and Wilcoxon rank test for continuous variables, N: Number of patients, SD: Standard deviation
Percentages are based on total number of patients in the analysis set with information.

Baseline characteristics by basal insulin treatment group at enrolment before propensity score matching - PRIMARY analysis set

	Before propensity score matching(N =1360)		
	Insulin Detemir (N =684)	Other Basal Insulin (N =676)	P-value
Norway	3 (0.4)	16 (2.4)	
Poland	16 (2.3)	35 (5.2)	
Portugal	2 (0.3)	11 (1.6)	
Romania	22 (3.2)	1 (0.1)	
Spain	26 (3.8)	78 (11.5)	
United Kingdom	92 (13.5)	98 (14.5)	
Type of diabetes, N (%)			
N	684	676	0.0002
TYPE 1	565 (82.6)	606 (89.6)	
TYPE 2	119 (17.4)	70 (10.4)	
History of diabetes complications, N (%)			
N	683	674	0.9579
Yes	165 (24.2)	162 (24.0)	
No	518 (75.8)	512 (76.0)	
History of hypertension, N (%)			
N	684	676	0.8162
Yes	57 (8.3)	54 (8.0)	
No	627 (91.7)	622 (92.0)	
Tobacco, N (%)			
N	668	652	0.0544
CURRENT SMOKER	63 (9.4)	63 (9.7)	
PREVIOUS SMOKER	82 (12.3)	110 (16.9)	
NEVER SMOKED	523 (78.3)	479 (73.5)	
Alcohol, N (%)			
N	658	636	0.7335
Yes	6 (0.9)	7 (1.1)	
No	652 (99.1)	629 (98.9)	
Education, N (%)			
N	638	621	0.0004
UNIVERSITY DEGREE	191 (29.9)	143 (23.0)	
COLLEGE DEGREE	83 (13.0)	108 (17.4)	
GRADUATE SCHOOL	123 (19.3)	87 (14.0)	
TECHNICAL SCHOOL	44 (6.9)	42 (6.8)	
HIGH SCHOOL	92 (14.4)	93 (15.0)	
A LEVELS	22 (3.4)	17 (2.7)	
INTERMEDIATE SCHOOL LEAVING CERTIFICATE	19 (3.0)	38 (6.1)	
BASIC SCHOOL LEAVING CERTIFICATE	20 (3.1)	26 (4.2)	
PRIMARY SCHOOL	6 (0.9)	13 (2.1)	
NO EDUCATION	3 (0.5)	11 (1.8)	
OTHER	35 (5.5)	43 (6.9)	
History of spontaneous abortion, N (%)			

Differences between treatment groups are tested using chi-square test for categorical variables and Wilcoxon rank test for continuous variables, N: Number of patients, SD: Standard deviation
Percentages are based on total number of patients in the analysis set with information.

Baseline characteristics by basal insulin treatment group at enrolment before propensity score matching - PRIMARY analysis set

	Before propensity score matching (N =1360)		
	Insulin Detemir (N =684)	Other Basal Insulin (N =676)	P-value
N	684	676	0.3951
Yes	163 (23.8)	148 (21.9)	
No	521 (76.2)	528 (78.1)	
History of caesarean section, N (%)			
N	684	676	0.0020
Yes	158 (23.1)	111 (16.4)	
No	526 (76.9)	565 (83.6)	
History of preterm delivery, N (%)			
N	684	676	0.3645
Yes	44 (6.4)	52 (7.7)	
No	640 (93.6)	624 (92.3)	
History of major malformations, N (%)			
N	684	676	0.9749
Yes	14 (2.0)	14 (2.1)	
No	670 (98.0)	662 (97.9)	
Number of previous pregnancies, N (%)			
N	684	676	0.5723
0	224 (32.7)	244 (36.1)	
1	250 (36.5)	229 (33.9)	
2	99 (14.5)	106 (15.7)	
3	59 (8.6)	52 (7.7)	
4+	52 (7.6)	45 (6.7)	
Folic acid supplementation initiated, N			
N	676	672	<0.001
Yes	432 (63.9)	546 (81.3)	
No	244 (36.1)	126 (18.8)	

Differences between treatment groups are tested using chi-square test for categorical variables and Wilcoxon rank test for continuous variables, N: Number of patients, SD: Standard deviation
Percentages are based on total number of patients in the analysis set with information.

14.1.34 Baseline characteristics by basal insulin treatment group at enrolment after propensity score matching - PRIMARY analysis set

	After propensity score matching(N =886)		
	Insulin Detemir (N =421)	Other Basal Insulin (N =465)	P-value
Age (years)			
N	421	465	0.1226
Mean (SD)	30.69 (5.04)	30.25 (5.29)	
Median	31.00	30.00	
2.5; 97.5 Percentiles	20.00 ; 40.00	19.00 ; 40.00	
Min ; Max	19.00 ; 44.00	17.00 ; 45.00	
Gestational age (weeks)			
N	421	465	0.7412
Mean (SD)	8.92 (2.42)	8.91 (2.48)	
Median	9.00	8.00	
2.5; 97.5 Percentiles	5.00 ; 14.00	5.00 ; 15.00	
Min ; Max	4.00 ; 16.00	3.00 ; 16.00	
Duration of DM (years)			
N	421	465	0.8469
Mean (SD)	13.94 (7.86)	13.94 (8.46)	
Median	13.00	13.00	
2.5; 97.5 Percentiles	2.00 ; 30.00	2.00 ; 30.00	
Min ; Max	1.00 ; 35.00	1.00 ; 38.00	
HbA1C (%)			
N	421	465	0.6997
Mean (SD)	7.05 (1.23)	7.09 (1.36)	
Median	6.82	6.73	
2.5; 97.5 Percentiles	5.40 ; 9.93	5.35 ; 10.50	
Min ; Max	4.40 ; 13.90	4.71 ; 13.60	
Body Mass Index (kg/m2)			
N	421	465	0.0724
Mean (SD)	26.09 (5.71)	26.58 (5.53)	
Median	24.60	25.20	
2.5; 97.5 Percentiles	19.00 ; 41.80	19.40 ; 40.50	
Min ; Max	16.30 ; 52.50	17.70 ; 49.00	
Country, N (%)			
N	421	465	<0.001
Croatia	100 (23.8)	38 (8.2)	
Denmark	120 (28.5)	186 (40.0)	
Finland	51 (12.1)	37 (8.0)	
France	6 (1.4)	6 (1.3)	
Germany	3 (0.7)	5 (1.1)	
Greece	2 (0.5)	6 (1.3)	
Ireland	28 (6.7)	17 (3.7)	
Israel	4 (1.0)	3 (0.6)	
Italy	13 (3.1)	13 (2.8)	
Malaysia	2 (0.5)	12 (2.6)	
Netherlands	6 (1.4)	2 (0.4)	

Differences between treatment groups are tested using chi-square test for categorical variables and Wilcoxon rank test for continuous variables, N: Number of patients, SD: Standard deviation
Percentages are based on total number of patients in the analysis set with information.

Baseline characteristics by basal insulin treatment group at enrolment after propensity score matching - PRIMARY analysis set

	After propensity score matching(N =886)		
	Insulin Detemir (N =421)	Other Basal Insulin (N =465)	P-value
Norway	0 (0.0)	10 (2.2)	
Poland	15 (3.6)	31 (6.7)	
Portugal	2 (0.5)	8 (1.7)	
Romania	3 (0.7)	1 (0.2)	
Spain	17 (4.0)	50 (10.8)	
United Kingdom	49 (11.6)	40 (8.6)	
Type of diabetes, N (%)			
N	421	465	0.3405
TYPE 1	369 (87.6)	417 (89.7)	
TYPE 2	52 (12.4)	48 (10.3)	
History of diabetes complications, N (%)			
N	421	465	0.0601
Yes	124 (29.5)	111 (23.9)	
No	297 (70.5)	354 (76.1)	
History of hypertension, N (%)			
N	421	465	0.6550
Yes	37 (8.8)	37 (8.0)	
No	384 (91.2)	428 (92.0)	
Tobacco, N (%)			
N	421	465	0.8892
CURRENT SMOKER	41 (9.7)	41 (8.8)	
PREVIOUS SMOKER	59 (14.0)	67 (14.4)	
NEVER SMOKED	321 (76.2)	357 (76.8)	
Alcohol, N (%)			
N	421	465	0.6321
Yes	4 (1.0)	6 (1.3)	
No	417 (99.0)	459 (98.7)	
Education, N (%)			
N	421	465	0.0274
UNIVERSITY DEGREE	106 (25.2)	108 (23.2)	
COLLEGE DEGREE	63 (15.0)	90 (19.4)	
GRADUATE SCHOOL	80 (19.0)	64 (13.8)	
TECHNICAL SCHOOL	30 (7.1)	28 (6.0)	
HIGH SCHOOL	59 (14.0)	73 (15.7)	
A LEVELS	18 (4.3)	14 (3.0)	
INTERMEDIATE SCHOOL LEAVING CERTIFICATE	14 (3.3)	33 (7.1)	
BASIC SCHOOL LEAVING CERTIFICATE	16 (3.8)	18 (3.9)	
PRIMARY SCHOOL	4 (1.0)	7 (1.5)	
NO EDUCATION	3 (0.7)	10 (2.2)	
OTHER	28 (6.7)	20 (4.3)	
History of spontaneous abortion, N (%)			

Differences between treatment groups are tested using chi-square test for categorical variables and Wilcoxon rank test for continuous variables, N: Number of patients, SD: Standard deviation
Percentages are based on total number of patients in the analysis set with information.

Baseline characteristics by basal insulin treatment group at enrolment after propensity score matching - PRIMARY analysis set

	After propensity score matching(N =886)		
	Insulin Detemir (N =421)	Other Basal Insulin (N =465)	P-value
N	421	465	0.6198
Yes	101 (24.0)	105 (22.6)	
No	320 (76.0)	360 (77.4)	
History of caesarean section, N (%)			
N	421	465	0.0234
Yes	90 (21.4)	72 (15.5)	
No	331 (78.6)	393 (84.5)	
History of preterm delivery, N (%)			
N	421	465	0.7001
Yes	28 (6.7)	34 (7.3)	
No	393 (93.3)	431 (92.7)	
History of major malformations, N (%)			
N	421	465	0.3078
Yes	8 (1.9)	5 (1.1)	
No	413 (98.1)	460 (98.9)	
Number of previous pregnancies, N (%)			
N	421	465	0.4642
0	141 (33.5)	172 (37.0)	
1	144 (34.2)	164 (35.3)	
2	62 (14.7)	67 (14.4)	
3	43 (10.2)	34 (7.3)	
4+	31 (7.4)	28 (6.0)	
Folic acid supplementation initiated, N			
N	421	465	0.0065
Yes	299 (71.0)	367 (78.9)	
No	122 (29.0)	98 (21.1)	

Differences between treatment groups are tested using chi-square test for categorical variables and Wilcoxon rank test for continuous variables, N: Number of patients, SD: Standard deviation
Percentages are based on total number of patients in the analysis set with information.

14.1.35 Observed HbA1c (%) during pregnancy in women treated with basal insulin detemir compared to other basal insulin – Summary – secondary effectiveness endpoint – MOTHER analysis set

	Insulin Detemir (N=727)	Other Basal Insulin (N=727)	Total (N=1454)
HBA1C at Conception			
N	261	249	510
Mean (SD)	7.1 (1.3)	7.3 (1.4)	7.2 (1.4)
Median	6.9	7.0	6.9
2.5; 97.5 percentiles	5.4 ;10.7	5.4 ;11.0	5.4 ;10.9
Min; Max	5.0 ;13.9	4.8 ;14.0	4.8 ;14.0
HBA1C < 6.5%			
N	261	249	510
Yes	94 (36.0)	78 (31.3)	172 (33.7)
No	167 (64.0)	171 (68.7)	338 (66.3)
HBA1C < 7.0%			
N	261	249	510
Yes	148 (56.7)	126 (50.6)	274 (53.7)
No	113 (43.3)	123 (49.4)	236 (46.3)

N: Number of patients, SD: Standard deviation
Percentages are based on total number of patients in the analysis set with information.

Observed HbA1c (%) during pregnancy in women treated with basal insulin detemir compared to other basal insulin – Summary – secondary effectiveness endpoint – MOTHER analysis set

	Insulin Detemir (N=727)	Other Basal Insulin (N=727)	Total (N=1454)
HBA1C at end of first trimester			
N	672	688	1360
Mean (SD)	6.5 (1.1)	6.7 (1.2)	6.6 (1.1)
Median	6.4	6.5	6.4
2.5; 97.5 percentiles	4.9 ;9.0	5.1 ;9.9	5.0 ;9.4
Min; Max	4.4 ;11.9	4.6 ;14.5	4.4 ;14.5
HBA1C < 6.5%			
N	672	688	1360
Yes	369 (54.9)	338 (49.1)	707 (52.0)
No	303 (45.1)	350 (50.9)	653 (48.0)
HBA1C < 7.0%			
N	672	688	1360
Yes	492 (73.2)	477 (69.3)	969 (71.3)
No	180 (26.8)	211 (30.7)	391 (28.8)

N: Number of patients, SD: Standard deviation
Percentages are based on total number of patients in the analysis set with information.

Observed HbA1c (%) during pregnancy in women treated with basal insulin detemir compared to other basal insulin – Summary – secondary effectiveness endpoint – MOTHER analysis set

	Insulin Detemir (N=727)	Other Basal Insulin (N=727)	Total (N=1454)
HBA1C at end of second trimester			
N	648	644	1292
Mean (SD)	6.1 (0.8)	6.2 (0.9)	6.2 (0.9)
Median	6.0	6.1	6.0
2.5; 97.5 percentiles	4.8 ;7.9	4.9 ;8.4	4.8 ;8.2
Min; Max	4.1 ;10.7	4.0 ;9.9	4.0 ;10.7
HBA1C < 6.5%			
N	648	644	1292
Yes	469 (72.4)	440 (68.3)	909 (70.4)
No	179 (27.6)	204 (31.7)	383 (29.6)
HBA1C < 7.0%			
N	648	644	1292
Yes	563 (86.9)	540 (83.9)	1103 (85.4)
No	85 (13.1)	104 (16.1)	189 (14.6)

N: Number of patients, SD: Standard deviation
Percentages are based on total number of patients in the analysis set with information.

Observed HbA1c (%) during pregnancy in women treated with basal insulin detemir compared to other basal insulin – Summary – secondary effectiveness endpoint – MOTHER analysis set

	Insulin Detemir (N=727)	Other Basal Insulin (N=727)	Total (N=1454)
HBA1C at end of third trimester			
N	351	421	772
Mean (SD)	6.3 (0.8)	6.2 (0.7)	6.2 (0.8)
Median	6.3	6.1	6.2
2.5; 97.5 percentiles	5.0 ;8.4	5.1 ;7.7	5.0 ;8.1
Min; Max	4.2 ;11.8	4.6 ;11.1	4.2 ;11.8
HBA1C < 6.5%			
N	351	421	772
Yes	226 (64.4)	296 (70.3)	522 (67.6)
No	125 (35.6)	125 (29.7)	250 (32.4)
HBA1C < 7.0%			
N	351	421	772
Yes	302 (86.0)	366 (86.9)	668 (86.5)
No	49 (14.0)	55 (13.1)	104 (13.5)

N: Number of patients, SD: Standard deviation
Percentages are based on total number of patients in the analysis set with information.

14.1.36 Estimated mean HbA1c (%) during pregnancy in women treated with basal insulin detemir compared to other basal insulin – statistical analysis – secondary effectiveness endpoint – MOTHER analysis set

	N	Estimate	SE	95% CI	P-value
Total participants = 1457					
Total observations included in the analysis = 1454					
Crude model					
HBA1C at Conception					
Insulin detemir	261	7.33	0.073		
Other basal insulin	249	7.48	0.074		
Treatment Difference					
Insulin detemir - Other basal insulin		-0.145	0.104	[-0.350 , 0.059]	0.1633
HBA1C at end of first trimester					
Insulin detemir	672	6.54	0.043		
Other basal insulin	688	6.72	0.043		

N: Number of patients
The response is analysed using a linear mixed model for repeated measurements with women as random effect, crude model (with fixed factors: time, basal insulin treatment group, interaction term (time * basal insulin treatment group)) and adjusted model (with fixed factors: country, age, gestational week, type of diabetes, duration of DM, history of diabetes complications, history of severe hypoglycaemia, history of foetal pregnancy complications, BMI, tobacco use, alcohol, education, bolus insulin, OAD and time and interaction term (time * basal insulin treatment group)).
Time have the values as start of pregnancy, end of first trimester, end of second trimester and end of third trimester.

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Estimated mean HbA1c (%) during pregnancy in women treated with basal insulin detemir compared to other basal insulin – statistical analysis – secondary effectiveness endpoint – MOTHER analysis set

	N	Estimate	SE	95% CI	P-value
Treatment Difference					
Insulin detemir - Other basal insulin		-0.181	0.061	[-0.300 , -0.062]	0.0029
HBA1C at end of second trimester					
Insulin detemir	648	6.11	0.033		
Other basal insulin	644	6.25	0.034		
Treatment Difference					
Insulin detemir - Other basal insulin		-0.139	0.047	[-0.232 , -0.046]	0.0034
HBA1C at end of third trimester					
Insulin detemir	351	6.27	0.036		
Other basal insulin	421	6.36	0.035		
Treatment Difference					
Insulin detemir - Other basal insulin		-0.085	0.051	[-0.184 , 0.014]	0.0932

N: Number of patients
The response is analysed using a linear mixed model for repeated measurements with women as random effect, crude model (with fixed factors: time, basal insulin treatment group, interaction term (time * basal insulin treatment group)) and adjusted model (with fixed factors: country, age, gestational week, type of diabetes, duration of DM, history of diabetes complications, history of severe hypoglycaemia, history of foetal pregnancy complications, BMI, tobacco use, alcohol, education, bolus insulin, OAD and time and interaction term (time * basal insulin treatment group)).
Time have the values as start of pregnancy, end of first trimester, end of second trimester and end of third trimester.

Estimated mean HbA1c (%) during pregnancy in women treated with basal insulin detemir compared to other basal insulin – statistical analysis – secondary effectiveness endpoint – MOTHER analysis set

	N	Estimate	SE	95% CI	P-value
Test for interaction					0.1842
Adjusted model					
HBA1C at Conception					
Insulin detemir	261	7.35	0.079		
Other basal insulin	249	7.40	0.084		
Treatment Difference					
Insulin detemir - Other basal insulin		-0.051	0.117	[-0.280 , 0.178]	0.6650
HBA1C at end of first trimester					
Insulin detemir	672	6.57	0.044		
Other basal insulin	688	6.64	0.047		
Treatment Difference					
Insulin detemir - Other basal insulin		-0.070	0.067	[-0.201 , 0.061]	0.2955

N: Number of patients
The response is analysed using a linear mixed model for repeated measurements with women as random effect, crude model (with fixed factors: time, basal insulin treatment group, interaction term (time * basal insulin treatment group)) and adjusted model (with fixed factors: country, age, gestational week, type of diabetes, duration of DM, history of diabetes complications, history of severe hypoglycaemia, history of foetal pregnancy complications, BMI, tobacco use, alcohol, education, bolus insulin, OAD and time and interaction term (time * basal insulin treatment group)).
Time have the values as start of pregnancy, end of first trimester, end of second trimester and end of third trimester.

Estimated mean HbA1c (%) during pregnancy in women treated with basal insulin detemir compared to other basal insulin – statistical analysis – secondary effectiveness endpoint – MOTHER analysis set

	N	Estimate	SE	95% CI	P-value
HBA1C at end of second trimester					
Insulin detemir	648	6.13	0.035		
Other basal insulin	644	6.14	0.038		
Treatment Difference					
Insulin detemir - Other basal insulin		-0.013	0.055	[-0.121 , 0.094]	0.8049
HBA1C at end of third trimester					
Insulin detemir	351	6.29	0.039		
Other basal insulin	421	6.28	0.041		
Treatment Difference					
Insulin detemir - Other basal insulin		0.015	0.060	[-0.101 , 0.132]	0.7960
Test for interaction					0.5055

N: Number of patients
The response is analysed using a linear mixed model for repeated measurements with women as random effect, crude model (with fixed factors: time, basal insulin treatment group, interaction term (time * basal insulin treatment group)) and adjusted model (with fixed factors: country, age, gestational week, type of diabetes, duration of DM, history of diabetes complications, history of severe hypoglycaemia, history of foetal pregnancy complications, BMI, tobacco use, alcohol, education, bolus insulin, OAD and time and interaction term (time * basal insulin treatment group)).
Time have the values as start of pregnancy, end of first trimester, end of second trimester and end of third trimester.

14.1.37 Hypoglycaemia during pregnancy in mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint – MOTHER analysis set

Value	N	Events	Risk/Odds		95% CI	P-value
N= 1394						
Before propensity score matching						
Levemir/Insulin Detemir	697	42	0.06/0.06			
Other Basal Insulin	697	63	0.09/0.10			
Insulin Detemir vs Other Basal Insulin						0.0419
Risk Difference				-0.030	(-0.058;-0.002)	
Odds Ratio				0.645	(0.430;0.968)	
N= 790						
After propensity score matching						
Levemir/Insulin Detemir	395	35	0.09/0.10			
Other Basal Insulin	395	28	0.07/0.08			
Insulin Detemir vs Other Basal Insulin						0.3701
Risk Difference				0.018	(-0.021;0.056)	
Odds Ratio				1.274	(0.759;2.139)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

14.1.38 Pre-eclampsia during pregnancy in mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - MOTHER analysis set

Value	N	Events	Risk/Odds		95% CI	P-value
N= 1401						
Before propensity score matching						
Levemir/Insulin Detemir	700	45	0.06/0.07			
Other Basal Insulin	701	70	0.10/0.11			
Insulin Detemir vs Other Basal Insulin						0.0192
Risk Difference				-0.036	(-0.064;-0.007)	
Odds Ratio				0.619	(0.419;0.915)	
N= 796						
After propensity score matching						
Levemir/Insulin Detemir	398	31	0.08/0.08			
Other Basal Insulin	398	38	0.10/0.11			
Insulin Detemir vs Other Basal Insulin						0.3853
Risk Difference				-0.018	(-0.057;0.022)	
Odds Ratio				0.800	(0.487;1.314)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

14.1.39 Perinatal death among foetus of mothers treated with basal insulin detemir compared to other basal insulins – statistical an alysis - secondary safety endpoint - FOETUS analysis set

Value	N	Events	Risk/Odds		95% CI	P-value
N= 1481						
Before propensity score matching						
Levemir/Insulin Detemir	741	6	0.01/0.01			
Other Basal Insulin	740	13	0.02/0.02			
Insulin Detemir vs Other Basal Insulin						0.1129
Risk Difference				-0.009	(-0.021;0.002)	
Odds Ratio				0.457	(0.173;1.208)	
N= 854						
After propensity score matching						
Levemir/Insulin Detemir	427	6	0.01/0.01			
Other Basal Insulin	427	5	0.01/0.01			
Insulin Detemir vs Other Basal Insulin						0.7630
Risk Difference				0.002	(-0.015;0.020)	
Odds Ratio				1.203	(0.364;3.972)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher’s exact test (crude analysis) and McNemar’s test for correlated binomial proportions (propensity score matched analysis).

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14.1.40 Neonatal death among foetus of mothers treated with basal insulin detemir compared to other basal insulins – statistical ana lysis - secondary safety endpoint - FOETUS analysis set

Value	N	Events	Risk/Odds		95% CI
N= 1449					
Before propensity score matching					
Levemir/Insulin Detemir	723	1	0.00/0.00		
Other Basal Insulin	726	0	0.00/0.00		
Insulin Detemir vs Other Basal Insulin					
Risk Difference				0.001	(-0.001;0.004)

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients

14.1.41 Induced abortion due to major malformation among foetus of mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - FOETUS analysis set

Organ	Value	N	Events	Risk/ Odds		95% CI	P-value
N= 1481							
Before propensity score matching							
Overall	Levemir/Insulin Detemir	741	5	0.01/ 0.01			
	Other Basal Insulin	740	9	0.01/ 0.01			
	Insulin Detemir vs Other Basal Insulin						0.2993
	Risk Difference				-0.005	(-0.015;0.004)	
	Odds Ratio				0.552	(0.184;1.654)	
Nervous system	Levemir/Insulin Detemir	741	2	0.00/ 0.00			
	Other Basal Insulin	740	5	0.01/ 0.01			
	Insulin Detemir vs Other Basal Insulin						0.2877
	Risk Difference				-0.004	(-0.011;0.003)	
	Odds Ratio				0.398	(0.077;2.057)	
Cardiovascular system	Levemir/Insulin Detemir	741	1	0.00/ 0.00			
	Other Basal Insulin	740	3	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						0.3742
	Risk Difference				-0.003	(-0.008;0.003)	
	Odds Ratio				0.332	(0.034;3.199)	
Genitourinary	Levemir/Insulin Detemir	741	1	0.00/ 0.00			

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher’s exact test (crude analysis) and McNemar’s test for correlated binomial proportions (propensity score matched analysis).

Induced abortion due to major malformation among foetus of mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - FOETUS analysis set

Organ	Value	N	Events	Risk/ Odds	95% CI	P-value
Genitourinary	Other Basal Insulin	740	1	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin					1.0000
	Risk Difference			-0.000	(-0.004;0.004)	
	Odds Ratio			0.999	(0.062;15.996)	
Vertebral	Levemir/Insulin Detemir	741	0	0.00/ 0.00		
	Other Basal Insulin	740	1	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin					
	Risk Difference			-0.001	(-0.004;0.001)	
Limbs	Levemir/Insulin Detemir	741	2	0.00/ 0.00		
	Other Basal Insulin	740	0	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin					
	Risk Difference			0.003	(-0.001;0.006)	
Eye, ear, face and neck	Levemir/Insulin Detemir	741	1	0.00/ 0.00		
	Other Basal Insulin	740	1	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin					1.0000
	Risk Difference			-0.000	(-0.004;0.004)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

Induced abortion due to major malformation among foetus of mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - FOETUS analysis set

Organ	Value	N	Events	Risk/ Odds	95% CI	P-value
Eye, ear, face and neck	Odds Ratio			0.999	(0.062;15.996)	
Respiratory	Levemir/Insulin Detemir	741	0	0.00/ 0.00		
	Other Basal Insulin	740	1	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin Risk Difference			-0.001	(-0.004;0.001)	
Endocrine glands	Levemir/Insulin Detemir	741	0	0.00/ 0.00		
	Other Basal Insulin	740	1	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin Risk Difference			-0.001	(-0.004;0.001)	
Other	Levemir/Insulin Detemir	741	0	0.00/ 0.00		
	Other Basal Insulin	740	1	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin Risk Difference			-0.001	(-0.004;0.001)	

N= 854
After propensity score matching

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher’s exact test (crude analysis) and McNemar’s test for correlated binomial proportions (propensity score matched analysis).

Induced abortion due to major malformation among foetus of mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - FOETUS analysis set

Organ	Value	N	Events	Risk/ Odds	95% CI	P-value
Overall	Levemir/Insulin Detemir	427	3	0.01/ 0.01		
	Other Basal Insulin	427	4	0.01/ 0.01		
	Insulin Detemir vs Other Basal Insulin					0.7055
	Risk Difference			-0.002	(-0.018;0.012)	
	Odds Ratio			0.748	(0.166;3.363)	
Nervous system	Levemir/Insulin Detemir	427	1	0.00/ 0.00		
	Other Basal Insulin	427	2	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin					0.5637
	Risk Difference			-0.002	(-0.015;0.009)	
	Odds Ratio			0.499	(0.045;5.522)	
Cardiovascular system	Levemir/Insulin Detemir	427	0	0.00/ 0.00		
	Other Basal Insulin	427	1	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin					
	Risk Difference			-0.002	(-0.013;0.007)	
Limbs	Levemir/Insulin Detemir	427	1	0.00/ 0.00		

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

Induced abortion due to major malformation among foetus of mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - FOETUS analysis set

Organ	Value	N	Events	Risk/ Odds	95% CI	P-value
Limbs	Other Basal Insulin	427	0	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin Risk Difference			0.002	(-0.007;0.013)	
Eye, ear, face and neck	Levemir/Insulin Detemir	427	1	0.00/ 0.00		
	Other Basal Insulin	427	1	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin					1.0000
	Risk Difference			0.000	(-0.011;0.011)	
	Odds Ratio			1.000	(0.062;16.040)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

14.1.42 Spontaneous abortion among foetus of mothers treated with basal insulin detemir compared to other basal insulins – statistic al analysis - secondary safety endpoint - FOETUS analysis set

Value	N	Events	Risk/Odds		95% CI	P-value
N= 1481						
Before propensity score matching						
Levemir/Insulin Detemir	741	40	0.05/0.06			
Other Basal Insulin	740	43	0.06/0.06			
Insulin Detemir vs Other Basal Insulin						0.7363
Risk Difference				-0.004	(-0.028;0.019)	
Odds Ratio				0.925	(0.594;1.441)	
N= 854						
After propensity score matching						
Levemir/Insulin Detemir	427	20	0.05/0.05			
Other Basal Insulin	427	24	0.06/0.06			
Insulin Detemir vs Other Basal Insulin						0.5465
Risk Difference				-0.009	(-0.040;0.021)	
Odds Ratio				0.825	(0.449;1.517)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher’s exact test (crude analysis) and McNemar’s test for correlated binomial proportions (propensity score matched analysis).

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14.1.43 Major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds	95% CI	P-value
N= 1348						
Before propensity score matching						
Overall	Levemir/Insulin Detemir	680	15	0.02/ 0.02		
	Other Basal Insulin	668	17	0.03/ 0.03		
	Insulin Detemir vs Other Basal Insulin					0.7232
	Risk Difference			-0.003	(-0.020;0.013)	
	Odds Ratio			0.864	(0.428;1.744)	
Nervous system	Levemir/Insulin Detemir	680	2	0.00/ 0.00		
	Other Basal Insulin	668	2	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin					1.0000
	Risk Difference			-0.000	(-0.006;0.006)	
	Odds Ratio			0.982	(0.138;6.994)	
Cardiovascular system	Levemir/Insulin Detemir	680	8	0.01/ 0.01		
	Other Basal Insulin	668	6	0.01/ 0.01		
	Insulin Detemir vs Other Basal Insulin					0.7895
	Risk Difference			0.003	(-0.008;0.014)	
	Odds Ratio			1.313	(0.453;3.806)	
Oro-facial	Levemir/Insulin Detemir	680	2	0.00/ 0.00		

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher’s exact test (crude analysis) and McNemar’s test for correlated binomial proportions (propensity score matched analysis).

Major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds		95% CI	P-value
Oro-facial	Other Basal Insulin	668	1	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						1.0000
	Risk Difference				0.001	(-0.004;0.006)	
	Odds Ratio				1.968	(0.178;21.750)	
Urinary	Levemir/Insulin Detemir	680	0	0.00/ 0.00			
	Other Basal Insulin	668	1	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						
	Risk Difference				-0.001	(-0.004;0.001)	
Genitourinary	Levemir/Insulin Detemir	680	2	0.00/ 0.00			
	Other Basal Insulin	668	7	0.01/ 0.01			
	Insulin Detemir vs Other Basal Insulin						0.1053
	Risk Difference				-0.008	(-0.016;0.001)	
	Odds Ratio				0.279	(0.058;1.346)	
Gastrointestinal	Levemir/Insulin Detemir	680	1	0.00/ 0.00			
	Other Basal Insulin	668	3	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						0.3700

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

Major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds		95% CI	P-value
Gastrointestinal	Risk Difference				-0.003	(-0.009;0.003)	
	Odds Ratio				0.326	(0.034;3.146)	
Vertebral	Levemir/Insulin Detemir	680	1	0.00/ 0.00			
	Other Basal Insulin	668	1	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						1.0000
	Risk Difference				-0.000	(-0.004;0.004)	
	Odds Ratio				0.982	(0.061;15.737)	
Limbs	Levemir/Insulin Detemir	680	2	0.00/ 0.00			
	Other Basal Insulin	668	0	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						
	Risk Difference				0.003	(-0.001;0.007)	
Eye, ear, face and neck	Levemir/Insulin Detemir	680	1	0.00/ 0.00			
	Other Basal Insulin	668	1	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						1.0000
	Risk Difference				-0.000	(-0.004;0.004)	
	Odds Ratio				0.982	(0.061;15.737)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher’s exact test (crude analysis) and McNemar’s test for correlated binomial proportions (propensity score matched analysis).

Major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds		95% CI	P-value
Respiratory	Levemir/Insulin Detemir	680	1	0.00/ 0.00			
	Other Basal Insulin	668	0	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						
	Risk Difference				0.001	(-0.001;0.004)	
Other	Levemir/Insulin Detemir	680	1	0.00/ 0.00			
	Other Basal Insulin	668	0	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						
	Risk Difference				0.001	(-0.001;0.004)	
N= 788							
After propensity score matching							
Overall	Levemir/Insulin Detemir	394	12	0.03/ 0.03			
	Other Basal Insulin	394	9	0.02/ 0.02			
	Insulin Detemir vs Other Basal Insulin						0.5127
	Risk Difference				0.008	(-0.016;0.032)	
	Odds Ratio				1.344	(0.560;3.226)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

Major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds		95% CI	P-value
Nervous system	Levemir/Insulin Detemir	394	2	0.01/ 0.01			
	Other Basal Insulin	394	2	0.01/ 0.01			
	Insulin Detemir vs Other Basal Insulin						1.0000
	Risk Difference				0.000	(-0.014;0.014)	
	Odds Ratio				1.000	(0.140;7.135)	
Cardiovascular system	Levemir/Insulin Detemir	394	7	0.02/ 0.02			
	Other Basal Insulin	394	3	0.01/ 0.01			
	Insulin Detemir vs Other Basal Insulin						0.2059
	Risk Difference				0.010	(-0.007;0.029)	
	Odds Ratio				2.357	(0.605;9.183)	
Oro-facial	Levemir/Insulin Detemir	394	1	0.00/ 0.00			
	Other Basal Insulin	394	0	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						
	Risk Difference				0.003	(-0.007;0.014)	
Genitourinary	Levemir/Insulin Detemir	394	2	0.01/ 0.01			

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher’s exact test (crude analysis) and McNemar’s test for correlated binomial proportions (propensity score matched analysis).

Major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds		95% CI	P-value
Genitourinary	Other Basal Insulin	394	4	0.01/ 0.01			
	Insulin Detemir vs Other Basal Insulin						0.4142
	Risk Difference				-0.005	(-0.021;0.010)	
	Odds Ratio				0.497	(0.091;2.732)	
Gastrointestinal	Levemir/Insulin Detemir	394	1	0.00/ 0.00			
	Other Basal Insulin	394	2	0.01/ 0.01			
	Insulin Detemir vs Other Basal Insulin						0.5637
	Risk Difference				-0.003	(-0.016;0.010)	
	Odds Ratio				0.499	(0.045;5.523)	
Eye, ear, face and neck	Levemir/Insulin Detemir	394	1	0.00/ 0.00			
	Other Basal Insulin	394	0	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						
	Risk Difference				0.003	(-0.007;0.014)	
Other	Levemir/Insulin Detemir	394	1	0.00/ 0.00			
	Other Basal Insulin	394	0	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

Major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds	95% CI	P-value
Other	Risk Difference			0.003	(-0.007;0.014)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

14.1.44 Minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds		95% CI	P-value
N= 1348							
Before propensity score matching							
Overall	Levemir/Insulin Detemir	680	49	0.07/ 0.08			
	Other Basal Insulin	668	68	0.10/ 0.11			
	Insulin Detemir vs Other Basal Insulin						0.0536
	Risk Difference				-0.030	(-0.060;0.000)	
	Odds Ratio				0.685	(0.467;1.006)	
Nervous system	Levemir/Insulin Detemir	680	1	0.00/ 0.00			
	Other Basal Insulin	668	1	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						1.0000
	Risk Difference				-0.000	(-0.004;0.004)	
	Odds Ratio				0.982	(0.061;15.737)	
Cardiovascular system	Levemir/Insulin Detemir	680	15	0.02/ 0.02			
	Other Basal Insulin	668	27	0.04/ 0.04			
	Insulin Detemir vs Other Basal Insulin						0.0600
	Risk Difference				-0.018	(-0.037;0.000)	
	Odds Ratio				0.536	(0.282;1.016)	
Oro-facial	Levemir/Insulin Detemir	680	5	0.01/ 0.01			

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher’s exact test (crude analysis) and McNemar’s test for correlated binomial proportions (propensity score matched analysis).

Minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds	95% CI	P-value
Oro-facial	Other Basal Insulin	668	9	0.01/ 0.01		
	Insulin Detemir vs Other Basal Insulin					0.2953
	Risk Difference			-0.006	(-0.017;0.005)	
	Odds Ratio			0.542	(0.181;1.627)	
Urinary	Levemir/Insulin Detemir	680	1	0.00/ 0.00		
	Other Basal Insulin	668	1	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin					1.0000
	Risk Difference			-0.000	(-0.004;0.004)	
	Odds Ratio			0.982	(0.061;15.737)	
Genitourinary	Levemir/Insulin Detemir	680	15	0.02/ 0.02		
	Other Basal Insulin	668	12	0.02/ 0.02		
	Insulin Detemir vs Other Basal Insulin					0.6985
	Risk Difference			0.004	(-0.011;0.019)	
	Odds Ratio			1.233	(0.573;2.654)	
Gastrointestinal	Levemir/Insulin Detemir	680	2	0.00/ 0.00		
	Other Basal Insulin	668	0	0.00/ 0.00		

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher’s exact test (crude analysis) and McNemar’s test for correlated binomial proportions (propensity score matched analysis).

Minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds	95% CI	P-value
Gastrointestinal	Insulin Detemir vs Other Basal Insulin					
	Risk Difference			0.003	(-0.001;0.007)	
Vertebral	Levemir/Insulin Detemir	680	1	0.00/ 0.00		
	Other Basal Insulin	668	3	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin					0.3700
	Risk Difference			-0.003	(-0.009;0.003)	
	Odds Ratio			0.326	(0.034;3.146)	
Limbs	Levemir/Insulin Detemir	680	6	0.01/ 0.01		
	Other Basal Insulin	668	7	0.01/ 0.01		
	Insulin Detemir vs Other Basal Insulin					0.7878
	Risk Difference			-0.002	(-0.012;0.009)	
	Odds Ratio			0.841	(0.281;2.514)	
Eye, ear, face and neck	Levemir/Insulin Detemir	680	2	0.00/ 0.00		
	Other Basal Insulin	668	8	0.01/ 0.01		
	Insulin Detemir vs Other Basal Insulin					0.0623
	Risk Difference			-0.009	(-0.018;0.000)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

Minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds		95% CI	P-value
Eye, ear, face and neck	Odds Ratio				0.243	(0.051;1.150)	
Respiratory	Levemir/Insulin Detemir	680	1	0.00/ 0.00			
	Other Basal Insulin	668	0	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin Risk Difference				0.001	(-0.001;0.004)	
Skin	Levemir/Insulin Detemir	680	4	0.01/ 0.01			
	Other Basal Insulin	668	6	0.01/ 0.01			
	Insulin Detemir vs Other Basal Insulin						0.5439
	Risk Difference				-0.003	(-0.012;0.006)	
	Odds Ratio				0.653	(0.183;2.324)	
Other	Levemir/Insulin Detemir	680	1	0.00/ 0.00			
	Other Basal Insulin	668	4	0.01/ 0.01			
	Insulin Detemir vs Other Basal Insulin						0.2139
	Risk Difference				-0.005	(-0.011;0.002)	
	Odds Ratio				0.244	(0.027;2.193)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

Minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds		95% CI	P-value
N= 788							
After propensity score matching							
Overall	Levemir/Insulin Detemir	394	30	0.08/ 0.08			
	Other Basal Insulin	394	45	0.11/ 0.13			
	Insulin Detemir vs Other Basal Insulin						0.0588
	Risk Difference				-0.038	(-0.080;0.003)	
	Odds Ratio				0.639	(0.394;1.038)	
Nervous system	Levemir/Insulin Detemir	394	1	0.00/ 0.00			
	Other Basal Insulin	394	1	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						1.0000
	Risk Difference				0.000	(-0.012;0.012)	
	Odds Ratio				1.000	(0.062;16.044)	
Cardiovascular system	Levemir/Insulin Detemir	394	7	0.02/ 0.02			
	Other Basal Insulin	394	18	0.05/ 0.05			
	Insulin Detemir vs Other Basal Insulin						0.0218
	Risk Difference				-0.028	(-0.055;-0.003)	
	Odds Ratio				0.378	(0.156;0.915)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher’s exact test (crude analysis) and McNemar’s test for correlated binomial proportions (propensity score matched analysis).

Minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds		95% CI	P-value
Oro-facial	Levemir/Insulin Detemir	394	3	0.01/ 0.01			
	Other Basal Insulin	394	6	0.02/ 0.02			
	Insulin Detemir vs Other Basal Insulin						0.3173
	Risk Difference				-0.008	(-0.026;0.009)	
	Odds Ratio				0.496	(0.123;1.998)	
Urinary	Levemir/Insulin Detemir	394	1	0.00/ 0.00			
	Other Basal Insulin	394	1	0.00/ 0.00			
	Insulin Detemir vs Other Basal Insulin						1.0000
	Risk Difference				0.000	(-0.012;0.012)	
	Odds Ratio				1.000	(0.062;16.044)	
Genitourinary	Levemir/Insulin Detemir	394	11	0.03/ 0.03			
	Other Basal Insulin	394	7	0.02/ 0.02			
	Insulin Detemir vs Other Basal Insulin						0.2850
	Risk Difference				0.010	(-0.012;0.033)	
	Odds Ratio				1.588	(0.609;4.139)	
Gastrointestinal	Levemir/Insulin Detemir	394	1	0.00/ 0.00			

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher’s exact test (crude analysis) and McNemar’s test for correlated binomial proportions (propensity score matched analysis).

Minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds	95% CI	P-value
Gastrointestinal	Other Basal Insulin	394	0	0.00/ 0.00		
	Insulin Detemir vs Other Basal Insulin Risk Difference			0.003	(-0.007;0.014)	
Vertebral	Levemir/Insulin Detemir	394	0	0.00/ 0.00		
	Other Basal Insulin	394	2	0.01/ 0.01		
	Insulin Detemir vs Other Basal Insulin Risk Difference			-0.005	(-0.018;0.005)	
Limbs	Levemir/Insulin Detemir	394	3	0.01/ 0.01		
	Other Basal Insulin	394	3	0.01/ 0.01		
	Insulin Detemir vs Other Basal Insulin					1.0000
	Risk Difference			0.000	(-0.015;0.015)	
	Odds Ratio			1.000	(0.201;4.985)	
Eye, ear, face and neck	Levemir/Insulin Detemir	394	1	0.00/ 0.00		
	Other Basal Insulin	394	7	0.02/ 0.02		
	Insulin Detemir vs Other Basal Insulin Risk Difference			-0.015	(-0.034;-0.000)	.

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

Minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Organ	Value	N	Events	Risk/ Odds	95% CI	P-value
Eye, ear, face and neck	Odds Ratio			0.141	(0.017;1.149)	
Skin	Levemir/Insulin Detemir	394	3	0.01/ 0.01		
	Other Basal Insulin	394	4	0.01/ 0.01		
	Insulin Detemir vs Other Basal Insulin					0.7055
	Risk Difference			-0.003	(-0.019;0.013)	
	Odds Ratio			0.748	(0.166;3.364)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

14.1.45 Foetal macrosomia among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins - LIVEBORN analysis set

Value	N	Events	Risk/Odds		95% CI	P-value
N= 1350						
Before propensity score matching						
Levemir/Insulin Detemir	682	125	0.18/0.22			
Other Basal Insulin	668	118	0.18/0.21			
Insulin Detemir vs Other Basal Insulin						0.7771
Risk Difference				0.007	(-0.034;0.048)	
Odds Ratio				1.046	(0.792;1.381)	
N= 790						
After propensity score matching						
Levemir/Insulin Detemir	395	77	0.19/0.24			
Other Basal Insulin	395	64	0.16/0.19			
Insulin Detemir vs Other Basal Insulin						0.2334
Risk Difference				0.033	(-0.021;0.086)	
Odds Ratio				1.252	(0.869;1.805)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

14.1.46 Large for gestational age among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - LIVEBORN analysis set

Value	N	Events	Risk/Odds		95% CI	P-value
N= 1285						
Before propensity score matching						
Levemir/Insulin Detemir	650	305	0.47/0.88			
Other Basal Insulin	635	326	0.51/1.06			
Insulin Detemir vs Other Basal Insulin						0.1184
Risk Difference				-0.044	(-0.099;0.010)	
Odds Ratio				0.838	(0.673;1.043)	
N= 768						
After propensity score matching						
Levemir/Insulin Detemir	384	193	0.50/1.01			
Other Basal Insulin	384	198	0.52/1.06			
Insulin Detemir vs Other Basal Insulin						0.7086
Risk Difference				-0.013	(-0.083;0.057)	
Odds Ratio				0.949	(0.715;1.260)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

14.1.47 Pre-term delivery among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins - LIVEBORN analysis set

Value	N	Events	Risk/Odds		95% CI	P-value
N= 1345						
Before propensity score matching						
Levemir/Insulin Detemir	681	182	0.27/0.36			
Other Basal Insulin	664	185	0.28/0.39			
Insulin Detemir vs Other Basal Insulin						0.6684
Risk Difference				-0.011	(-0.059;0.036)	
Odds Ratio				0.944	(0.743;1.200)	
N= 788						
After propensity score matching						
Levemir/Insulin Detemir	394	111	0.28/0.39			
Other Basal Insulin	394	104	0.26/0.36			
Insulin Detemir vs Other Basal Insulin						0.5788
Risk Difference				0.018	(-0.044;0.080)	
Odds Ratio				1.094	(0.799;1.497)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher's exact test (crude analysis) and McNemar's test for correlated binomial proportions (propensity score matched analysis).

14.1.48 Diabetes at 1 year of age among infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - INFANT analysis set

Value	N	Events	Risk/Odds		95% CI	P-value
N= 1259						
Before propensity score matching						
Levemir/Insulin Detemir	632	2	0.0032/0.0032			
Other Basal Insulin	627	2	0.0032/0.0032			
Insulin Detemir vs Other Basal Insulin						1.0000
Risk Difference				-0.000	(-0.006;0.006)	
Odds Ratio				0.992	(0.139;7.065)	
N= 736						
After propensity score matching						
Levemir/Insulin Detemir	368	2	0.0054/0.0055			
Other Basal Insulin	368	2	0.0054/0.0055			
Insulin Detemir vs Other Basal Insulin						1.0000
Risk Difference				0.000	(-0.015;0.015)	
Odds Ratio				1.000	(0.140;7.137)	

CI: Confidence interval, 95% CI is constructed using propensity score matched analysis by Newcombe method, N: Number of patients
Differences between basal insulin treatment groups at enrolment are tested by Fisher’s exact test (crude analysis) and McNemar’s test for correlated binomial proportions (propensity score matched analysis).

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14.1.49 Height and weight at 1 year of age among infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - INFANT analysis set

	N	Estimate	SE	95% CI	P-value
Height (cm)					
Number of observations in the analysis = 1139					
Crude model					
Insulin detemir	581	76.52			
Other basal insulin	558	76.34			
Insulin detemir - Other basal insulin		0.18	0.27	[-0.34 , 0.71]	0.4970
Adjusted model					
Insulin detemir	581	76.45			
Other basal insulin	558	76.60			
Insulin detemir - Other basal insulin		-0.16	0.31	[-0.76 , 0.45]	0.6127
Weight (gram)					
Number of observations in the analysis = 1175					
Crude model					
Insulin detemir	593	10103.66			
Other basal insulin	582	9975.69			
Insulin detemir - Other basal insulin		127.97	78.05	[-25.15 , 281.10]	0.1013
Adjusted model					

Covariates used for crude model are basal insulin treatment group and that for adjusted model are country, basal insulin treatment group, age of mother, type of diabetes of mother, previous lactation, educational level of mother, N: Number of patients, Regression crude and fully adjusted models are performed

Height and weight at 1 year of age among infants born to mothers treated with basal insulin detemir compared to other basal insulins – statistical analysis - secondary safety endpoint - INFANT analysis set

	N	Estimate	SE	95% CI	P-value
Insulin detemir	593	10046.30			
Other basal insulin	582	10069.52			
Insulin detemir - Other basal insulin		-23.22	90.99	[-201.75 , 155.32]	0.7986

Covariates used for crude model are basal insulin treatment group and that for adjusted model are country, basal insulin treatment group, age of mother, type of diabetes of mother, previous lactation, educational level of mother, N: Number of patients, Regression crude and fully adjusted models are performed

14.1.50 SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Total number of patients	764	828	781	2373
Total number of patients with events	282 (36.9)	392 (47.3)	423 (54.2)	1097 (46.2)
Blood and lymphatic system disorders	5 (0.7)	3 (0.4)	7 (0.9)	15 (0.6)
Anaemia deficiencies	1 (0.1)			1 (0.1)
Anaemia of pregnancy	1 (0.1)			1 (0.1)
Anaemias NEC	3 (0.4)	3 (0.4)	5 (0.6)	11 (0.5)
Anaemia	3 (0.4)	3 (0.4)	5 (0.6)	11 (0.5)
Spleen disorders	1 (0.1)			1 (0.1)
Splenic haematoma	1 (0.1)			1 (0.1)
Thrombocytopenias			2 (0.3)	2 (0.1)
Thrombocytopenia			2 (0.3)	2 (0.1)
Cardiac disorders	2 (0.3)	12 (1.4)	18 (2.3)	32 (1.3)
Ischaemic coronary artery disorders		1 (0.1)		1 (0.1)
Myocardial infarction		1 (0.1)		1 (0.1)
Mitral valvular disorders			1 (0.1)	1 (0.1)
Mitral valve incompetence			1 (0.1)	1 (0.1)
Myocardial disorders NEC			2 (0.3)	2 (0.1)
Left ventricular dilatation			1 (0.1)	1 (0.1)
Left ventricular hypertrophy			1 (0.1)	1 (0.1)
Rate and rhythm disorders NEC	2 (0.3)	11 (1.3)	15 (1.9)	28 (1.2)
Bradycardia foetal	1 (0.1)	2 (0.2)	3 (0.4)	6 (0.3)
Foetal arrhythmia	1 (0.1)	4 (0.5)	6 (0.8)	11 (0.5)
Foetal heart rate deceleration abnormality		1 (0.1)	1 (0.1)	2 (0.1)
Foetal heart rate disorder			3 (0.4)	3 (0.1)
Tachycardia		1 (0.1)	2 (0.3)	3 (0.1)

N: Number of patients with one or more events, %: percentage of patients with one or more events
MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Tachycardia foetal		3 (0.4)	1 (0.1)	4 (0.2)
Tachycardia paroxysmal			1 (0.1)	1 (0.1)
Ventricular arrhythmias and cardiac arrest			1 (0.1)	1 (0.1)
Cardiac arrest			1 (0.1)	1 (0.1)
Congenital, familial and genetic disorders	20 (2.6)	18 (2.2)	20 (2.6)	58 (2.4)
Arterial disorders congenital	1 (0.1)		3 (0.4)	4 (0.2)
Congenital arterial malformation			1 (0.1)	1 (0.1)
Pulmonary artery stenosis congenital			1 (0.1)	1 (0.1)
Single umbilical artery	1 (0.1)		2 (0.3)	3 (0.1)
Autosomal chromosomal abnormalities	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
Trisomy 18	1 (0.1)	1 (0.1)		2 (0.1)
Trisomy 21		1 (0.1)	1 (0.1)	2 (0.1)
Cardiac disorders congenital NEC		1 (0.1)	2 (0.3)	3 (0.1)
Endocardial fibroelastosis			1 (0.1)	1 (0.1)
Heart disease congenital		1 (0.1)	1 (0.1)	2 (0.1)
Cardiac hypoplasias congenital	1 (0.1)			1 (0.1)
Hypoplastic right heart syndrome	1 (0.1)			1 (0.1)
Cardiac septal defects congenital	3 (0.4)	3 (0.4)	4 (0.5)	10 (0.4)
Atrioventricular septal defect		1 (0.1)		1 (0.1)
Ventricular septal defect	3 (0.4)	2 (0.2)	4 (0.5)	9 (0.4)
Cardiac valve disorders congenital			1 (0.1)	1 (0.1)
Bicuspid aortic valve			1 (0.1)	1 (0.1)
Cardiovascular disorders congenital NEC			1 (0.1)	1 (0.1)
Congenital cardiovascular anomaly			1 (0.1)	1 (0.1)
Central nervous system disorders congenital NEC	3 (0.4)	2 (0.2)		5 (0.2)
Brain malformation	3 (0.4)	1 (0.1)		4 (0.2)
Encephalocele		1 (0.1)		1 (0.1)
Cerebellar disorders congenital	1 (0.1)			1 (0.1)

N: Number of patients with one or more events, %: percentage of patients with one or more events
MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Cerebellar hypoplasia	1 (0.1)			1 (0.1)
Cerebral disorders congenital	1 (0.1)	3 (0.4)	2 (0.3)	6 (0.3)
Anencephaly		1 (0.1)		1 (0.1)
Congenital cerebral cyst			1 (0.1)	1 (0.1)
Congenital choroid plexus cyst			1 (0.1)	1 (0.1)
Congenital hydrocephalus		2 (0.2)		2 (0.1)
Holoprosencephaly	1 (0.1)			1 (0.1)
Chromosomal abnormalities NEC	2 (0.3)		1 (0.1)	3 (0.1)
Confined placental mosaicism	1 (0.1)			1 (0.1)
Foetal chromosome abnormality	1 (0.1)		1 (0.1)	2 (0.1)
Congenital disorders NEC	3 (0.4)	2 (0.2)	1 (0.1)	6 (0.3)
Congenital anomaly in offspring			1 (0.1)	1 (0.1)
Foetal malformation	2 (0.3)	2 (0.2)		4 (0.2)
Multiple congenital abnormalities	1 (0.1)			1 (0.1)
Gastrointestinal tract disorders congenital NEC			1 (0.1)	1 (0.1)
Gastroschisis			1 (0.1)	1 (0.1)
Great vessel disorders congenital	1 (0.1)		2 (0.3)	3 (0.1)
Congenital aortic stenosis			1 (0.1)	1 (0.1)
Transposition of the great vessels	1 (0.1)			1 (0.1)
Truncus arteriosus persistent			1 (0.1)	1 (0.1)
Intestinal disorders congenital		1 (0.1)		1 (0.1)
Congenital large intestinal atresia		1 (0.1)		1 (0.1)
Lymphatic system disorders congenital			1 (0.1)	1 (0.1)
Cystic lymphangioma			1 (0.1)	1 (0.1)
Lysosomal storage disorders			1 (0.1)	1 (0.1)
Tay-Sachs disease			1 (0.1)	1 (0.1)
Musculoskeletal and connective tissue disorders of limbs congenital	2 (0.3)			2 (0.1)
Congenital hand malformation	1 (0.1)			1 (0.1)
Talipes	1 (0.1)			1 (0.1)

N: Number of patients with one or more events, %: percentage of patients with one or more events
MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Musculoskeletal and connective tissue disorders of skull congenital	1 (0.1)	1 (0.1)		2 (0.1)
Congenital absence of cranial vault	1 (0.1)			1 (0.1)
Microcephaly		1 (0.1)		1 (0.1)
Musculoskeletal and connective tissue disorders of spine congenital		1 (0.1)	1 (0.1)	2 (0.1)
Hemivertebra			1 (0.1)	1 (0.1)
Spine malformation		1 (0.1)		1 (0.1)
Non-site specific cartilage disorders congenital			1 (0.1)	1 (0.1)
Chondrodystrophy			1 (0.1)	1 (0.1)
Renal and urinary tract disorders congenital NEC		1 (0.1)		1 (0.1)
Congenital hydronephrosis		1 (0.1)		1 (0.1)
Renal disorders congenital	5 (0.7)	3 (0.4)	1 (0.1)	9 (0.4)
Congenital cystic kidney disease	1 (0.1)			1 (0.1)
Congenital pyelocaliectasis		1 (0.1)	1 (0.1)	2 (0.1)
Ectopic kidney		1 (0.1)		1 (0.1)
Kidney duplex	1 (0.1)			1 (0.1)
Kidney malformation		1 (0.1)		1 (0.1)
Renal aplasia	2 (0.3)			2 (0.1)
Renal hypoplasia	1 (0.1)			1 (0.1)
Ureteric disorders congenital			1 (0.1)	1 (0.1)
Double ureter			1 (0.1)	1 (0.1)
Viral infections congenital		1 (0.1)		1 (0.1)
Congenital cytomegalovirus infection		1 (0.1)		1 (0.1)
Ear and labyrinth disorders	1 (0.1)		1 (0.1)	2 (0.1)
Inner ear signs and symptoms	1 (0.1)		1 (0.1)	2 (0.1)
Vertigo	1 (0.1)			1 (0.1)
Vertigo positional			1 (0.1)	1 (0.1)
Endocrine disorders			2 (0.3)	2 (0.1)

N: Number of patients with one or more events, %: percentage of patients with one or more events
MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Adrenal cortical hypofunctions			1 (0.1)	1 (0.1)
Adrenal insufficiency			1 (0.1)	1 (0.1)
Anterior pituitary hypofunction			1 (0.1)	1 (0.1)
Hypopituitarism			1 (0.1)	1 (0.1)
Eye disorders	1 (0.1)	3 (0.4)	3 (0.4)	7 (0.3)
Choroid and vitreous haemorrhages and vascular disorders	1 (0.1)			1 (0.1)
Vitreous haemorrhage	1 (0.1)			1 (0.1)
Ocular bleeding and vascular disorders NEC			1 (0.1)	1 (0.1)
Eye haemorrhage			1 (0.1)	1 (0.1)
Ocular nerve and muscle disorders			1 (0.1)	1 (0.1)
Strabismus			1 (0.1)	1 (0.1)
Ocular sensation disorders			1 (0.1)	1 (0.1)
Photophobia			1 (0.1)	1 (0.1)
Retinal bleeding and vascular disorders (excl retinopathy)		1 (0.1)		1 (0.1)
Retinal haemorrhage		1 (0.1)		1 (0.1)
Retinopathies NEC		2 (0.2)		2 (0.1)
Diabetic retinopathy		1 (0.1)		1 (0.1)
Retinopathy		1 (0.1)		1 (0.1)
Visual disorders NEC			1 (0.1)	1 (0.1)
Vision blurred			1 (0.1)	1 (0.1)
Gastrointestinal disorders	26 (3.4)	25 (3.0)	31 (4.0)	82 (3.5)
Colitis (excl infective)	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Colitis	1 (0.1)			1 (0.1)
Colitis ulcerative		1 (0.1)	2 (0.3)	3 (0.1)
Diarrhoea (excl infective)	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
Diarrhoea	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
Gastritis (excl infective)		1 (0.1)		1 (0.1)

N: Number of patients with one or more events, %: percentage of patients with one or more events
MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Gastritis		1 (0.1)		1 (0.1)
Gastrointestinal and abdominal pains (excl oral and throat)	6 (0.8)	12 (1.4)	10 (1.3)	28 (1.2)
Abdominal pain	5 (0.7)	9 (1.1)	7 (0.9)	21 (0.9)
Abdominal pain lower			2 (0.3)	2 (0.1)
Abdominal pain upper	1 (0.1)	3 (0.4)	1 (0.1)	5 (0.2)
Gastrointestinal atonic and hypomotility disorders NEC	1 (0.1)			1 (0.1)
Constipation	1 (0.1)			1 (0.1)
Gastrointestinal stenosis and obstruction NEC	1 (0.1)			1 (0.1)
Intestinal obstruction	1 (0.1)			1 (0.1)
Intestinal haemorrhages	1 (0.1)			1 (0.1)
Rectal haemorrhage	1 (0.1)			1 (0.1)
Nausea and vomiting symptoms	20 (2.6)	10 (1.2)	19 (2.4)	49 (2.1)
Nausea	4 (0.5)		2 (0.3)	6 (0.3)
Vomiting	18 (2.4)	10 (1.2)	18 (2.3)	46 (1.9)
General disorders and administration site conditions	8 (1.0)	10 (1.2)	18 (2.3)	36 (1.5)
Asthenic conditions	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Asthenia			1 (0.1)	1 (0.1)
Malaise	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
Body temperature altered		1 (0.1)		1 (0.1)
Hyperthermia		1 (0.1)		1 (0.1)
Death and sudden death		4 (0.5)	2 (0.3)	6 (0.3)
Death neonatal		3 (0.4)	2 (0.3)	5 (0.2)
Electrocution		1 (0.1)		1 (0.1)
Febrile disorders			3 (0.4)	3 (0.1)
Pyrexia			3 (0.4)	3 (0.1)
Feelings and sensations NEC	1 (0.1)			1 (0.1)
Feeling abnormal	1 (0.1)			1 (0.1)
General signs and symptoms NEC	3 (0.4)	1 (0.1)	4 (0.5)	8 (0.3)

N: Number of patients with one or more events, %: percentage of patients with one or more events
MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Macrosomia	2 (0.3)	1 (0.1)	3 (0.4)	6 (0.3)
Peripheral swelling	1 (0.1)			1 (0.1)
Swelling			1 (0.1)	1 (0.1)
Oedema NEC	2 (0.3)	2 (0.2)	6 (0.8)	10 (0.4)
Generalised oedema	1 (0.1)	1 (0.1)		2 (0.1)
Oedema	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Oedema peripheral			4 (0.5)	4 (0.2)
Pain and discomfort NEC	1 (0.1)	1 (0.1)		2 (0.1)
Chest discomfort		1 (0.1)		1 (0.1)
Chest pain	1 (0.1)			1 (0.1)
Therapeutic and nontherapeutic responses			1 (0.1)	1 (0.1)
Adverse drug reaction			1 (0.1)	1 (0.1)
Hepatobiliary disorders	4 (0.5)	5 (0.6)	6 (0.8)	15 (0.6)
Bile duct infections and inflammations		1 (0.1)		1 (0.1)
Biliary colic		1 (0.1)		1 (0.1)
Cholecystitis and cholelithiasis	1 (0.1)		3 (0.4)	4 (0.2)
Cholecystitis			1 (0.1)	1 (0.1)
Cholecystitis chronic	1 (0.1)			1 (0.1)
Cholelithiasis			2 (0.3)	2 (0.1)
Cholestasis and jaundice	2 (0.3)	1 (0.1)	3 (0.4)	6 (0.3)
Cholestasis	1 (0.1)		1 (0.1)	2 (0.1)
Cholestasis of pregnancy	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Hepatic and hepatobiliary disorders NEC		2 (0.2)		2 (0.1)
Liver disorder		2 (0.2)		2 (0.1)
Hepatic vascular disorders	1 (0.1)			1 (0.1)
Hepatic haematoma	1 (0.1)			1 (0.1)
Hepatocellular damage and hepatitis NEC		1 (0.1)		1 (0.1)
Hepatocellular injury		1 (0.1)		1 (0.1)

N: Number of patients with one or more events, %: percentage of patients with one or more events
MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Infections and infestations	26 (3.4)	32 (3.9)	32 (4.1)	90 (3.8)
Abdominal and gastrointestinal infections	7 (0.9)	9 (1.1)	10 (1.3)	26 (1.1)
Appendicitis		1 (0.1)		1 (0.1)
Appendicitis perforated			1 (0.1)	1 (0.1)
Gastroenteritis	7 (0.9)	8 (1.0)	9 (1.2)	24 (1.0)
Bacterial infections NEC			1 (0.1)	1 (0.1)
Cellulitis			1 (0.1)	1 (0.1)
Bordetella infections			1 (0.1)	1 (0.1)
Pertussis			1 (0.1)	1 (0.1)
Breast infections	1 (0.1)			1 (0.1)
Mastitis	1 (0.1)			1 (0.1)
Caliciviral infections			1 (0.1)	1 (0.1)
Gastroenteritis norovirus			1 (0.1)	1 (0.1)
Cytomegaloviral infections	1 (0.1)			1 (0.1)
Cytomegalovirus infection	1 (0.1)			1 (0.1)
Dental and oral soft tissue infections	1 (0.1)			1 (0.1)
Tooth abscess	1 (0.1)			1 (0.1)
Ear infections	1 (0.1)			1 (0.1)
Labyrinthitis	1 (0.1)			1 (0.1)
Escherichia infections	1 (0.1)	2 (0.2)		3 (0.1)
Escherichia urinary tract infection	1 (0.1)	2 (0.2)		3 (0.1)
Eye and eyelid infections			1 (0.1)	1 (0.1)
Corneal abscess			1 (0.1)	1 (0.1)
Female reproductive tract infections	2 (0.3)	3 (0.4)	2 (0.3)	7 (0.3)
Amniotic cavity infection	2 (0.3)	2 (0.2)		4 (0.2)
Bartholinitis			1 (0.1)	1 (0.1)
Puerperal pyrexia		1 (0.1)		1 (0.1)
Uterine infection			1 (0.1)	1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Infections NEC	1 (0.1)	3 (0.4)	2 (0.3)	6 (0.3)
Abscess		1 (0.1)		1 (0.1)
Abscess limb		1 (0.1)		1 (0.1)
Injection site abscess			1 (0.1)	1 (0.1)
Respiratory tract infection	1 (0.1)	1 (0.1)		2 (0.1)
Wound abscess			1 (0.1)	1 (0.1)
Influenza viral infections		3 (0.4)	2 (0.3)	5 (0.2)
Influenza		3 (0.4)	2 (0.3)	5 (0.2)
Lower respiratory tract and lung infections		2 (0.2)	1 (0.1)	3 (0.1)
Bronchitis		1 (0.1)		1 (0.1)
Lower respiratory tract infection		1 (0.1)		1 (0.1)
Pneumonia			1 (0.1)	1 (0.1)
Sepsis, bacteraemia, viraemia and fungaemia NEC		1 (0.1)	1 (0.1)	2 (0.1)
Septic shock			1 (0.1)	1 (0.1)
Urosepsis		1 (0.1)		1 (0.1)
Skin structures and soft tissue infections	1 (0.1)			1 (0.1)
Pilonidal cyst	1 (0.1)			1 (0.1)
Streptococcal infections	1 (0.1)		1 (0.1)	2 (0.1)
Beta haemolytic streptococcal infection			1 (0.1)	1 (0.1)
Streptococcal urinary tract infection	1 (0.1)			1 (0.1)
Upper respiratory tract infections	1 (0.1)	3 (0.4)	2 (0.3)	6 (0.3)
Laryngitis		1 (0.1)		1 (0.1)
Sinusitis		1 (0.1)		1 (0.1)
Tonsillitis	1 (0.1)			1 (0.1)
Upper respiratory tract infection		1 (0.1)	2 (0.3)	3 (0.1)
Urinary tract infections	6 (0.8)	5 (0.6)	7 (0.9)	18 (0.8)
Cystitis	1 (0.1)			1 (0.1)
Pyelonephritis	2 (0.3)	1 (0.1)	2 (0.3)	5 (0.2)
Pyelonephritis acute	1 (0.1)	1 (0.1)		2 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Renal abscess	1 (0.1)			1 (0.1)
Urinary tract infection	2 (0.3)	3 (0.4)	5 (0.6)	10 (0.4)
Viral infections NEC	3 (0.4)	2 (0.2)	2 (0.3)	7 (0.3)
Vestibular neuronitis		1 (0.1)	1 (0.1)	2 (0.1)
Viral infection	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
Viral upper respiratory tract infection	1 (0.1)			1 (0.1)
Injury, poisoning and procedural complications	4 (0.5)	7 (0.8)	8 (1.0)	19 (0.8)
Anaesthetic and allied procedural complications		1 (0.1)		1 (0.1)
Anaesthetic complication cardiac		1 (0.1)		1 (0.1)
Limb fractures and dislocations	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
Ankle fracture		1 (0.1)	1 (0.1)	2 (0.1)
Femoral neck fracture	1 (0.1)			1 (0.1)
Foot fracture	1 (0.1)			1 (0.1)
Hand fracture	1 (0.1)			1 (0.1)
Non-site specific injuries NEC	1 (0.1)	2 (0.2)	4 (0.5)	7 (0.3)
Fall		2 (0.2)	3 (0.4)	5 (0.2)
Road traffic accident	1 (0.1)		1 (0.1)	2 (0.1)
Non-site specific procedural complications	2 (0.3)		2 (0.3)	4 (0.2)
Post procedural haematoma			1 (0.1)	1 (0.1)
Post procedural haemorrhage	1 (0.1)			1 (0.1)
Postoperative hypotension	1 (0.1)			1 (0.1)
Procedural haemorrhage			1 (0.1)	1 (0.1)
Reproductive system and breast injuries		3 (0.4)	1 (0.1)	4 (0.2)
Perineal injury		2 (0.2)		2 (0.1)
Uterine rupture		1 (0.1)	1 (0.1)	2 (0.1)
Skin injuries NEC	1 (0.1)			1 (0.1)
Subcutaneous haematoma	1 (0.1)			1 (0.1)
Thoracic cage fractures and dislocations	1 (0.1)			1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

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Rib fracture	1 (0.1)			1 (0.1)
Investigations	21 (2.7)	31 (3.7)	42 (5.4)	94 (4.0)
Blood gas and acid base analyses	1 (0.1)			1 (0.1)
Blood pH decreased	1 (0.1)			1 (0.1)
Carbohydrate tolerance analyses (incl diabetes)	7 (0.9)	7 (0.8)	8 (1.0)	22 (0.9)
Blood glucose abnormal	1 (0.1)	3 (0.4)	2 (0.3)	6 (0.3)
Blood glucose fluctuation	3 (0.4)	4 (0.5)	5 (0.6)	12 (0.5)
Blood glucose increased	2 (0.3)		1 (0.1)	3 (0.1)
Glycosylated haemoglobin increased	1 (0.1)			1 (0.1)
Foetal and neonatal diagnostic procedures	7 (0.9)	12 (1.4)	19 (2.4)	38 (1.6)
Amniotic fluid index abnormal	1 (0.1)			1 (0.1)
Amniotic fluid index decreased			1 (0.1)	1 (0.1)
Amniotic fluid volume decreased			1 (0.1)	1 (0.1)
Amniotic fluid volume increased		1 (0.1)	1 (0.1)	2 (0.1)
Foetal heart rate abnormal	2 (0.3)	4 (0.5)	4 (0.5)	10 (0.4)
Foetal heart rate decreased	1 (0.1)	1 (0.1)	3 (0.4)	5 (0.2)
Foetal monitoring		3 (0.4)	2 (0.3)	5 (0.2)
Foetal monitoring abnormal	3 (0.4)	3 (0.4)	7 (0.9)	13 (0.5)
Foetal and neonatal imaging procedures		2 (0.2)	3 (0.4)	5 (0.2)
Foetal renal imaging abnormal		1 (0.1)		1 (0.1)
Ultrasound foetal abnormal		1 (0.1)	3 (0.4)	4 (0.2)
Imaging procedures NEC	1 (0.1)			1 (0.1)
Ultrasound scan abnormal	1 (0.1)			1 (0.1)
Investigations NEC			2 (0.3)	2 (0.1)
Diagnostic procedure			2 (0.3)	2 (0.1)
Investigation			1 (0.1)	1 (0.1)
Liver function analyses			3 (0.4)	3 (0.1)
Hepatic enzyme increased			3 (0.4)	3 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

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Metabolism tests NEC		2 (0.2)	1 (0.1)	3 (0.1)
Blood ketone body present		1 (0.1)		1 (0.1)
Urine ketone body present		1 (0.1)	1 (0.1)	2 (0.1)
Physical examination procedures and organ system status	2 (0.3)	5 (0.6)	1 (0.1)	8 (0.3)
Medical observation	1 (0.1)	3 (0.4)	1 (0.1)	5 (0.2)
Weight increased	1 (0.1)	2 (0.2)		3 (0.1)
Urinalysis NEC		1 (0.1)		1 (0.1)
Nitrite urine present		1 (0.1)		1 (0.1)
Vascular imaging procedures NEC			1 (0.1)	1 (0.1)
Directional Doppler flow tests abnormal			1 (0.1)	1 (0.1)
Vascular tests NEC (incl blood pressure)	3 (0.4)	5 (0.6)	7 (0.9)	15 (0.6)
Blood pressure increased	3 (0.4)	5 (0.6)	6 (0.8)	14 (0.6)
Blood pressure measurement			1 (0.1)	1 (0.1)
Virus identification and serology	1 (0.1)	1 (0.1)		2 (0.1)
HIV antibody positive	1 (0.1)			1 (0.1)
Influenza A virus test		1 (0.1)		1 (0.1)
Metabolism and nutrition disorders	47 (6.2)	80 (9.7)	90 (11.5)	217 (9.1)
Diabetes mellitus (incl subtypes)	15 (2.0)	35 (4.2)	47 (6.0)	97 (4.1)
Decreased insulin requirement	4 (0.5)	7 (0.8)	8 (1.0)	19 (0.8)
Diabetes mellitus			3 (0.4)	3 (0.1)
Diabetes mellitus inadequate control	11 (1.4)	27 (3.3)	36 (4.6)	74 (3.1)
Increased insulin requirement		1 (0.1)		1 (0.1)
Diabetic complications NEC	13 (1.7)	6 (0.7)	9 (1.2)	28 (1.2)
Diabetic ketoacidosis	12 (1.6)	6 (0.7)	7 (0.9)	25 (1.1)
Diabetic ketosis		1 (0.1)	1 (0.1)	2 (0.1)
Diabetic metabolic decompensation	1 (0.1)		1 (0.1)	2 (0.1)
General nutritional disorders NEC			1 (0.1)	1 (0.1)
Abnormal weight gain			1 (0.1)	1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

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Hyperglycaemic conditions NEC	1 (0.1)	2 (0.2)	3 (0.4)	6 (0.3)
Hyperglycaemia	1 (0.1)	2 (0.2)	3 (0.4)	6 (0.3)
Hypoglycaemic conditions NEC	23 (3.0)	38 (4.6)	37 (4.7)	98 (4.1)
Hypoglycaemia	23 (3.0)	38 (4.6)	37 (4.7)	98 (4.1)
Hypoglycaemia unawareness		1 (0.1)		1 (0.1)
Iron deficiencies			1 (0.1)	1 (0.1)
Iron deficiency			1 (0.1)	1 (0.1)
Metabolic acidoses (excl diabetic acidoses)	1 (0.1)	5 (0.6)		6 (0.3)
Ketoacidosis	1 (0.1)	2 (0.2)		3 (0.1)
Ketosis		3 (0.4)		3 (0.1)
Metabolic disorders NEC	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
Metabolic disorder	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
Mixed acid-base disorders	1 (0.1)			1 (0.1)
Acidosis	1 (0.1)			1 (0.1)
Total fluid volume decreased			2 (0.3)	2 (0.1)
Dehydration			2 (0.3)	2 (0.1)
Total fluid volume increased		1 (0.1)		1 (0.1)
Fluid retention		1 (0.1)		1 (0.1)
Vitamin deficiencies NEC			1 (0.1)	1 (0.1)
Hypovitaminosis			1 (0.1)	1 (0.1)
Musculoskeletal and connective tissue disorders	1 (0.1)	4 (0.5)	2 (0.3)	7 (0.3)
Bone related signs and symptoms			1 (0.1)	1 (0.1)
Pubic pain			1 (0.1)	1 (0.1)
Joint related signs and symptoms			1 (0.1)	1 (0.1)
Arthralgia			1 (0.1)	1 (0.1)
Musculoskeletal and connective tissue pain and discomfort	1 (0.1)	4 (0.5)		5 (0.2)
Back pain		4 (0.5)		4 (0.2)
Musculoskeletal pain	1 (0.1)			1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

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Neoplasms benign, malignant and unspecified (incl cysts and polyps)		2 (0.2)	2 (0.3)	4 (0.2)
Breast and nipple neoplasms malignant		1 (0.1)		1 (0.1)
Breast cancer		1 (0.1)		1 (0.1)
Hepatobiliary neoplasms benign			1 (0.1)	1 (0.1)
Hepatic adenoma			1 (0.1)	1 (0.1)
Ovarian neoplasms malignant (excl germ cell)		1 (0.1)		1 (0.1)
Ovarian cancer		1 (0.1)		1 (0.1)
Ovarian epithelial cancer		1 (0.1)		1 (0.1)
Reproductive neoplasms female benign NEC			1 (0.1)	1 (0.1)
Benign hydatidiform mole			1 (0.1)	1 (0.1)
Nervous system disorders	13 (1.7)	19 (2.3)	16 (2.0)	48 (2.0)
Central nervous system haemorrhages and cerebrovascular accidents	1 (0.1)		1 (0.1)	2 (0.1)
Cerebrovascular accident	1 (0.1)		1 (0.1)	2 (0.1)
Central nervous system vascular disorders NEC		1 (0.1)		1 (0.1)
Foetal cerebrovascular disorder		1 (0.1)		1 (0.1)
Coma states			1 (0.1)	1 (0.1)
Hypoglycaemic coma			1 (0.1)	1 (0.1)
Disturbances in consciousness NEC		3 (0.4)	2 (0.3)	5 (0.2)
Hypoglycaemic unconsciousness		3 (0.4)	1 (0.1)	4 (0.2)
Lethargy			1 (0.1)	1 (0.1)
Generalised tonic-clonic seizures	1 (0.1)			1 (0.1)
Generalised tonic-clonic seizure	1 (0.1)			1 (0.1)
Headaches NEC	4 (0.5)	5 (0.6)	8 (1.0)	17 (0.7)
Headache	4 (0.5)	5 (0.6)	8 (1.0)	17 (0.7)
Hydrocephalic conditions	1 (0.1)			1 (0.1)
Hydrocephalus	1 (0.1)			1 (0.1)
Lumbar spinal cord and nerve root disorders		1 (0.1)		1 (0.1)

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SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

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Sciatica		1 (0.1)		1 (0.1)
Migraine headaches	2 (0.3)	2 (0.2)		4 (0.2)
Migraine	2 (0.3)	2 (0.2)		4 (0.2)
Neurological signs and symptoms NEC	1 (0.1)	2 (0.2)	2 (0.3)	5 (0.2)
Dizziness	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Presyncope		1 (0.1)		1 (0.1)
Paraesthesias and dysaesthesias	1 (0.1)		1 (0.1)	2 (0.1)
Hypoaesthesia	1 (0.1)			1 (0.1)
Paraesthesia			1 (0.1)	1 (0.1)
Seizures and seizure disorders NEC	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
Epilepsy	1 (0.1)			1 (0.1)
Hypoglycaemic seizure		1 (0.1)	1 (0.1)	2 (0.1)
Seizure	1 (0.1)			1 (0.1)
Sensory abnormalities NEC		1 (0.1)		1 (0.1)
Neuralgia		1 (0.1)		1 (0.1)
Structural brain disorders NEC	1 (0.1)		1 (0.1)	2 (0.1)
Cerebral ventricle dilatation	1 (0.1)		1 (0.1)	2 (0.1)
Transient cerebrovascular events		3 (0.4)		3 (0.1)
Transient ischaemic attack		3 (0.4)		3 (0.1)
Pregnancy, puerperium and perinatal conditions	177 (23.2)	241 (29.1)	259 (33.2)	677 (28.5)
Abortion related conditions and complications	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
Anembryonic gestation	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
Abortions not specified as induced or spontaneous	28 (3.7)	19 (2.3)	24 (3.1)	71 (3.0)
Abortion	8 (1.0)	7 (0.8)	5 (0.6)	20 (0.8)
Abortion incomplete			1 (0.1)	1 (0.1)
Abortion missed	20 (2.6)	12 (1.4)	18 (2.3)	50 (2.1)
Abortions spontaneous	20 (2.6)	25 (3.0)	22 (2.8)	67 (2.8)
Abortion spontaneous	20 (2.6)	25 (3.0)	21 (2.7)	66 (2.8)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

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Abortion threatened		1 (0.1)		1 (0.1)
Imminent abortion			1 (0.1)	1 (0.1)
Amniotic fluid and cavity disorders of pregnancy NEC	10 (1.3)	13 (1.6)	14 (1.8)	37 (1.6)
Amniorrhexis	2 (0.3)	1 (0.1)		3 (0.1)
Amniorrhoea			1 (0.1)	1 (0.1)
Meconium in amniotic fluid		1 (0.1)	1 (0.1)	2 (0.1)
Meconium stain	1 (0.1)			1 (0.1)
Oligohydramnios	2 (0.3)	3 (0.4)	3 (0.4)	8 (0.3)
Polyhydramnios	5 (0.7)	8 (1.0)	9 (1.2)	22 (0.9)
Failed labour	7 (0.9)	9 (1.1)	13 (1.7)	29 (1.2)
Arrested labour	5 (0.7)	5 (0.6)	4 (0.5)	14 (0.6)
Failed induction of labour	2 (0.3)	3 (0.4)	9 (1.2)	14 (0.6)
False labour		1 (0.1)		1 (0.1)
Foetal complications NEC	22 (2.9)	30 (3.6)	32 (4.1)	84 (3.5)
Foetal cardiac disorder	1 (0.1)		2 (0.3)	3 (0.1)
Foetal disorder	2 (0.3)	6 (0.7)	5 (0.6)	13 (0.5)
Foetal distress syndrome	5 (0.7)	16 (1.9)	11 (1.4)	32 (1.3)
Foetal hypokinesia	14 (1.8)	8 (1.0)	14 (1.8)	36 (1.5)
Foetal growth complications	3 (0.4)	6 (0.7)	12 (1.5)	21 (0.9)
Foetal growth restriction		3 (0.4)	7 (0.9)	10 (0.4)
Foetal macrosomia	3 (0.4)	3 (0.4)	5 (0.6)	11 (0.5)
Foetal position and presentation abnormalities	1 (0.1)	2 (0.2)	5 (0.6)	8 (0.3)
Asynclitic presentation			1 (0.1)	1 (0.1)
Breech presentation	1 (0.1)		3 (0.4)	4 (0.2)
Foetal malposition		1 (0.1)		1 (0.1)
Transverse presentation		1 (0.1)		1 (0.1)
Unstable foetal lie			1 (0.1)	1 (0.1)
Gestational age and weight conditions	2 (0.3)	4 (0.5)	10 (1.3)	16 (0.7)
Large for dates baby	1 (0.1)	3 (0.4)	8 (1.0)	12 (0.5)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

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Premature baby		1 (0.1)		1 (0.1)
Small for dates baby	1 (0.1)		2 (0.3)	3 (0.1)
Haemorrhagic complications of pregnancy	7 (0.9)	3 (0.4)	7 (0.9)	17 (0.7)
Haemorrhage in pregnancy	3 (0.4)	1 (0.1)	1 (0.1)	5 (0.2)
Placenta praevia haemorrhage	2 (0.3)		2 (0.3)	4 (0.2)
Premature separation of placenta	2 (0.3)	2 (0.2)	4 (0.5)	8 (0.3)
Retroplacental haematoma			1 (0.1)	1 (0.1)
High risk pregnancies		2 (0.2)		2 (0.1)
High risk pregnancy		2 (0.2)		2 (0.1)
Hypertension associated disorders of pregnancy	44 (5.8)	75 (9.1)	82 (10.5)	201 (8.5)
Eclampsia	1 (0.1)		2 (0.3)	3 (0.1)
Gestational hypertension	3 (0.4)	9 (1.1)	8 (1.0)	20 (0.8)
HELLP syndrome	5 (0.7)	3 (0.4)	1 (0.1)	9 (0.4)
Pre-eclampsia	37 (4.8)	64 (7.7)	73 (9.3)	174 (7.3)
Labour onset and length abnormalities	32 (4.2)	33 (4.0)	35 (4.5)	100 (4.2)
Premature delivery	9 (1.2)	7 (0.8)	6 (0.8)	22 (0.9)
Premature labour	8 (1.0)	6 (0.7)	8 (1.0)	22 (0.9)
Premature rupture of membranes	7 (0.9)	8 (1.0)	12 (1.5)	27 (1.1)
Prolonged labour	2 (0.3)	3 (0.4)		5 (0.2)
Prolonged rupture of membranes			1 (0.1)	1 (0.1)
Threatened labour	6 (0.8)	9 (1.1)	11 (1.4)	26 (1.1)
Maternal complications of delivery NEC			1 (0.1)	1 (0.1)
Retained placenta or membranes			1 (0.1)	1 (0.1)
Maternal complications of labour NEC	7 (0.9)	8 (1.0)	6 (0.8)	21 (0.9)
Cephalo-pelvic disproportion	3 (0.4)	1 (0.1)		4 (0.2)
Intrapartum haemorrhage	2 (0.3)			2 (0.1)
Uterine contractions abnormal	1 (0.1)	4 (0.5)	2 (0.3)	7 (0.3)
Uterine hypertonus		3 (0.4)	2 (0.3)	5 (0.2)
Uterine hypotonus	1 (0.1)		1 (0.1)	2 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Uterine tachysystole			1 (0.1)	1 (0.1)
Maternal complications of pregnancy NEC	8 (1.0)	11 (1.3)	10 (1.3)	29 (1.2)
Cervical incompetence		2 (0.2)	2 (0.3)	4 (0.2)
Hyperemesis gravidarum	4 (0.5)	7 (0.8)	6 (0.8)	17 (0.7)
Morning sickness	3 (0.4)		1 (0.1)	4 (0.2)
Preterm premature rupture of membranes	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
Normal pregnancy, labour and delivery	7 (0.9)		4 (0.5)	11 (0.5)
Uterine contractions during pregnancy	7 (0.9)		4 (0.5)	11 (0.5)
Placental abnormalities (excl neoplasms)	2 (0.3)	4 (0.5)	3 (0.4)	9 (0.4)
Placenta praevia	1 (0.1)			1 (0.1)
Placental disorder			3 (0.4)	3 (0.1)
Placental insufficiency	1 (0.1)	4 (0.5)		5 (0.2)
Postpartum complications NEC	2 (0.3)	8 (1.0)	12 (1.5)	22 (0.9)
Postpartum haemorrhage	2 (0.3)	8 (1.0)	12 (1.5)	22 (0.9)
Stillbirth and foetal death	8 (1.0)	13 (1.6)	14 (1.8)	35 (1.5)
Foetal death	8 (1.0)	12 (1.4)	13 (1.7)	33 (1.4)
Stillbirth		1 (0.1)	2 (0.3)	3 (0.1)
Umbilical cord complications	1 (0.1)	3 (0.4)		4 (0.2)
Umbilical cord prolapse		1 (0.1)		1 (0.1)
Umbilical cord vascular disorder	1 (0.1)	2 (0.2)		3 (0.1)
Psychiatric disorders	3 (0.4)		1 (0.1)	4 (0.2)
Brief psychotic disorder			1 (0.1)	1 (0.1)
Brief psychotic disorder, with postpartum onset			1 (0.1)	1 (0.1)
Mental disorders NEC	1 (0.1)			1 (0.1)
Mental disorder	1 (0.1)			1 (0.1)
Mood alterations with depressive symptoms	1 (0.1)			1 (0.1)
Depressed mood	1 (0.1)			1 (0.1)
Panic attacks and disorders	1 (0.1)			1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Panic attack	1 (0.1)			1 (0.1)
Suicidal and self-injurious behaviour	1 (0.1)			1 (0.1)
Suicidal ideation	1 (0.1)			1 (0.1)
Renal and urinary disorders	7 (0.9)	13 (1.6)	11 (1.4)	31 (1.3)
Nephropathies and tubular disorders NEC		1 (0.1)	2 (0.3)	3 (0.1)
Diabetic nephropathy		1 (0.1)	1 (0.1)	2 (0.1)
Nephropathy			1 (0.1)	1 (0.1)
Renal failure and impairment	2 (0.3)	2 (0.2)		4 (0.2)
Chronic kidney disease		1 (0.1)		1 (0.1)
Renal failure	1 (0.1)	1 (0.1)		2 (0.1)
Renal impairment	1 (0.1)			1 (0.1)
Renal hypertension and related conditions			1 (0.1)	1 (0.1)
Hypertensive nephropathy			1 (0.1)	1 (0.1)
Renal obstructive disorders		1 (0.1)		1 (0.1)
Hydronephrosis		1 (0.1)		1 (0.1)
Urinary abnormalities	5 (0.7)	6 (0.7)	7 (0.9)	18 (0.8)
Glycosuria			1 (0.1)	1 (0.1)
Ketonuria		1 (0.1)	1 (0.1)	2 (0.1)
Microalbuminuria		1 (0.1)		1 (0.1)
Proteinuria	5 (0.7)	4 (0.5)	6 (0.8)	15 (0.6)
Urinary tract signs and symptoms NEC		4 (0.5)	1 (0.1)	5 (0.2)
Renal colic		3 (0.4)	1 (0.1)	4 (0.2)
Renal pain		1 (0.1)		1 (0.1)
Reproductive system and breast disorders	17 (2.2)	9 (1.1)	12 (1.5)	38 (1.6)
Cervix disorders NEC	5 (0.7)	1 (0.1)	4 (0.5)	10 (0.4)
Cervix disorder	2 (0.3)		1 (0.1)	3 (0.1)
Shortened cervix	3 (0.4)		4 (0.5)	7 (0.3)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Uterine cervical erosion		1 (0.1)		1 (0.1)
Menstruation and uterine bleeding NEC		1 (0.1)		1 (0.1)
Metrorrhagia		1 (0.1)		1 (0.1)
Pelvis and broad ligament disorders NEC	1 (0.1)			1 (0.1)
Pelvic haematoma	1 (0.1)			1 (0.1)
Reproductive tract signs and symptoms NEC	1 (0.1)	1 (0.1)		2 (0.1)
Pelvic pain	1 (0.1)	1 (0.1)		2 (0.1)
Uterine disorders NEC	1 (0.1)			1 (0.1)
Uterine haemorrhage	1 (0.1)			1 (0.1)
Vulvovaginal disorders NEC	10 (1.3)	5 (0.6)	8 (1.0)	23 (1.0)
Vaginal haemorrhage	10 (1.3)	5 (0.6)	8 (1.0)	23 (1.0)
Vulvovaginal signs and symptoms		1 (0.1)		1 (0.1)
Vaginal discharge		1 (0.1)		1 (0.1)
Respiratory, thoracic and mediastinal disorders	6 (0.8)	7 (0.8)	7 (0.9)	20 (0.8)
Breathing abnormalities		2 (0.2)	2 (0.3)	4 (0.2)
Dyspnoea		2 (0.2)	2 (0.3)	4 (0.2)
Bronchospasm and obstruction	1 (0.1)		1 (0.1)	2 (0.1)
Asthma			1 (0.1)	1 (0.1)
Asthmatic crisis	1 (0.1)			1 (0.1)
Conditions associated with abnormal gas exchange	1 (0.1)			1 (0.1)
Asphyxia	1 (0.1)			1 (0.1)
Coughing and associated symptoms		1 (0.1)		1 (0.1)
Cough		1 (0.1)		1 (0.1)
Lower respiratory tract signs and symptoms	1 (0.1)			1 (0.1)
Pleuritic pain	1 (0.1)			1 (0.1)
Neonatal hypoxic conditions	2 (0.3)	3 (0.4)	1 (0.1)	6 (0.3)
Neonatal asphyxia	2 (0.3)	3 (0.4)	1 (0.1)	6 (0.3)
Pulmonary oedemas			2 (0.3)	2 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Acute pulmonary oedema			1 (0.1)	1 (0.1)
Pulmonary oedema			1 (0.1)	1 (0.1)
Pulmonary thrombotic and embolic conditions			1 (0.1)	1 (0.1)
Pulmonary embolism			1 (0.1)	1 (0.1)
Upper respiratory tract signs and symptoms	1 (0.1)	1 (0.1)		2 (0.1)
Catarrh	1 (0.1)			1 (0.1)
Oropharyngeal pain		1 (0.1)		1 (0.1)
Skin and subcutaneous tissue disorders			1 (0.1)	1 (0.1)
Pruritus NEC			1 (0.1)	1 (0.1)
Pruritus			1 (0.1)	1 (0.1)
Rashes, eruptions and exanthems NEC			1 (0.1)	1 (0.1)
Rash			1 (0.1)	1 (0.1)
Surgical and medical procedures	29 (3.8)	41 (5.0)	56 (7.2)	126 (5.3)
Cervix therapeutic procedures		2 (0.2)		2 (0.1)
Cervix cerclage procedure		2 (0.2)		2 (0.1)
Hormonal therapeutic procedures NEC	2 (0.3)	3 (0.4)	4 (0.5)	9 (0.4)
Steroid therapy	2 (0.3)	3 (0.4)	4 (0.5)	9 (0.4)
Induced abortions	7 (0.9)	7 (0.8)	13 (1.7)	27 (1.1)
Abortion induced	7 (0.9)	7 (0.8)	13 (1.7)	27 (1.1)
Mastectomies		1 (0.1)		1 (0.1)
Mastectomy		1 (0.1)		1 (0.1)
Obstetric therapeutic procedures	20 (2.6)	28 (3.4)	33 (4.2)	81 (3.4)
Caesarean section	18 (2.4)	24 (2.9)	25 (3.2)	67 (2.8)
Evacuation of retained products of conception			1 (0.1)	1 (0.1)
Labour induction	2 (0.3)		4 (0.5)	6 (0.3)
Maternal therapy to enhance foetal lung maturity		1 (0.1)	1 (0.1)	2 (0.1)
Retained placenta operation		1 (0.1)	1 (0.1)	2 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among mothers – FAS_MOTHER

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Vacuum extractor delivery		2 (0.2)	1 (0.1)	3 (0.1)
Therapeutic procedures NEC		1 (0.1)	7 (0.9)	8 (0.3)
Diabetes mellitus management		1 (0.1)	5 (0.6)	6 (0.3)
Hospitalisation			2 (0.3)	2 (0.1)
Vascular disorders	13 (1.7)	15 (1.8)	11 (1.4)	39 (1.6)
Non-site specific embolism and thrombosis			1 (0.1)	1 (0.1)
Thrombosis			1 (0.1)	1 (0.1)
Peripheral embolism and thrombosis		1 (0.1)		1 (0.1)
Deep vein thrombosis		1 (0.1)		1 (0.1)
Vascular hypertensive disorders NEC	13 (1.7)	14 (1.7)	10 (1.3)	37 (1.6)
Hypertension	13 (1.7)	14 (1.7)	10 (1.3)	37 (1.6)

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MedDRA version - 22.1.

14.1.51 SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants – FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Total number of patients	773	828	795	2396
Total number of patients with events	237 (30.7)	328 (39.6)	321 (40.4)	886 (37.0)
Blood and lymphatic system disorders	4 (0.5)	3 (0.4)	12 (1.5)	19 (0.8)
Anaemia deficiencies	1 (0.1)			1 (0.1)
Iron deficiency anaemia	1 (0.1)			1 (0.1)
Anaemias NEC	2 (0.3)	2 (0.2)	3 (0.4)	7 (0.3)
Anaemia	2 (0.3)			2 (0.1)
Anaemia neonatal		2 (0.2)	3 (0.4)	5 (0.2)
Coagulopathies			1 (0.1)	1 (0.1)
Disseminated intravascular coagulation			1 (0.1)	1 (0.1)
Eosinophilic disorders			1 (0.1)	1 (0.1)
Eosinophilia			1 (0.1)	1 (0.1)
Leukopenias NEC			1 (0.1)	1 (0.1)
Lymphopenia			1 (0.1)	1 (0.1)
Neutropenias			1 (0.1)	1 (0.1)
Febrile neutropenia			1 (0.1)	1 (0.1)
Polycythaemia (excl rubra vera)	1 (0.1)		3 (0.4)	4 (0.2)
Polycythaemia	1 (0.1)			1 (0.1)
Polycythaemia neonatorum			3 (0.4)	3 (0.1)
Thrombocytopenias		1 (0.1)	3 (0.4)	4 (0.2)
Thrombocytopenia		1 (0.1)	1 (0.1)	2 (0.1)
Thrombocytopenia neonatal			2 (0.3)	2 (0.1)
Cardiac disorders	7 (0.9)	7 (0.8)	11 (1.4)	25 (1.0)
Aortic valvular disorders			1 (0.1)	1 (0.1)
Aortic valve stenosis			1 (0.1)	1 (0.1)
Cardiac signs and symptoms NEC	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Cyanosis	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Heart failures NEC	2 (0.3)			2 (0.1)
Cardiac failure	2 (0.3)			2 (0.1)
Mitral valvular disorders		1 (0.1)	2 (0.3)	3 (0.1)
Mitral valve incompetence		1 (0.1)	2 (0.3)	3 (0.1)
Myocardial disorders NEC		2 (0.2)	6 (0.8)	8 (0.3)
Cardiac hypertrophy		1 (0.1)	1 (0.1)	2 (0.1)
Cardiac septal hypertrophy			1 (0.1)	1 (0.1)
Left ventricular hypertrophy			4 (0.5)	4 (0.2)
Ventricle rupture		1 (0.1)		1 (0.1)
Pericardial disorders NEC	1 (0.1)			1 (0.1)
Pneumopericardium	1 (0.1)			1 (0.1)
Pulmonary valvular disorders	1 (0.1)	1 (0.1)		2 (0.1)
Pulmonary valve stenosis	1 (0.1)	1 (0.1)		2 (0.1)
Rate and rhythm disorders NEC	2 (0.3)	1 (0.1)		3 (0.1)
Bradycardia		1 (0.1)		1 (0.1)
Bradycardia neonatal	2 (0.3)			2 (0.1)
Supraventricular arrhythmias		1 (0.1)		1 (0.1)
Supraventricular tachycardia		1 (0.1)		1 (0.1)
Tricuspid valvular disorders			1 (0.1)	1 (0.1)
Tricuspid valve incompetence			1 (0.1)	1 (0.1)
Ventricular arrhythmias and cardiac arrest			1 (0.1)	1 (0.1)
Ventricular arrhythmia			1 (0.1)	1 (0.1)
Congenital, familial and genetic disorders	61 (7.9)	87 (10.5)	83 (10.4)	231 (9.6)
Anaemias congenital (excl haemoglobinopathies)	1 (0.1)		2 (0.3)	3 (0.1)
ABO haemolytic disease of newborn	1 (0.1)		2 (0.3)	3 (0.1)
Anorectal disorders congenital	1 (0.1)	1 (0.1)		2 (0.1)
Anal atresia	1 (0.1)			1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Anterior displaced anus		1 (0.1)		1 (0.1)
Arterial disorders congenital	1 (0.1)	2 (0.2)	3 (0.4)	6 (0.3)
Pulmonary artery stenosis congenital		2 (0.2)	3 (0.4)	5 (0.2)
Single umbilical artery	1 (0.1)			1 (0.1)
Bladder disorders congenital		1 (0.1)		1 (0.1)
Congenital bladder anomaly		1 (0.1)		1 (0.1)
Breast disorders congenital		1 (0.1)		1 (0.1)
Supernumerary nipple		1 (0.1)		1 (0.1)
Cardiac disorders congenital NEC	2 (0.3)	3 (0.4)	1 (0.1)	6 (0.3)
Heart disease congenital	2 (0.3)	2 (0.2)	1 (0.1)	5 (0.2)
Left ventricular false tendon		1 (0.1)		1 (0.1)
Cardiac hypoplasias congenital	1 (0.1)			1 (0.1)
Hypoplastic right heart syndrome	1 (0.1)			1 (0.1)
Cardiac septal defects congenital	15 (1.9)	21 (2.5)	33 (4.2)	69 (2.9)
Atrial septal defect	10 (1.3)	13 (1.6)	21 (2.6)	44 (1.8)
Atrioventricular septal defect			1 (0.1)	1 (0.1)
Cardiac septal defect			1 (0.1)	1 (0.1)
Hypertrophic cardiomyopathy	1 (0.1)		5 (0.6)	6 (0.3)
Left-to-right cardiac shunt		1 (0.1)		1 (0.1)
Ventricular septal defect	5 (0.6)	8 (1.0)	9 (1.1)	22 (0.9)
Cardiac valve disorders congenital	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
Congenital aortic valve stenosis			1 (0.1)	1 (0.1)
Congenital pulmonary valve atresia	1 (0.1)			1 (0.1)
Congenital tricuspid valve incompetence		1 (0.1)		1 (0.1)
Congenital tricuspid valve stenosis	1 (0.1)			1 (0.1)
Central nervous system disorders congenital NEC	1 (0.1)	1 (0.1)		2 (0.1)
Brain malformation	1 (0.1)			1 (0.1)
Congenital spinal cord anomaly		1 (0.1)		1 (0.1)
Cerebral disorders congenital	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Cerebral palsy		1 (0.1)	1 (0.1)	2 (0.1)
Congenital choroid plexus cyst			1 (0.1)	1 (0.1)
Congenital hydrocephalus	1 (0.1)			1 (0.1)
Holoprosencephaly	1 (0.1)			1 (0.1)
Chromosomal abnormalities NEC	2 (0.3)		2 (0.3)	4 (0.2)
Cytogenetic abnormality	1 (0.1)		1 (0.1)	2 (0.1)
Foetal chromosome abnormality			1 (0.1)	1 (0.1)
Gene mutation	1 (0.1)			1 (0.1)
Congenital disorders NEC		3 (0.4)	1 (0.1)	4 (0.2)
Congenital dermal sinus		1 (0.1)		1 (0.1)
Multiple congenital abnormalities		2 (0.2)	1 (0.1)	3 (0.1)
Ear disorders congenital NEC			2 (0.3)	2 (0.1)
Ear malformation			2 (0.3)	2 (0.1)
Endocrine disorders congenital NEC		2 (0.2)		2 (0.1)
Diabetic foetopathy		2 (0.2)		2 (0.1)
External ear disorders congenital			1 (0.1)	1 (0.1)
Accessory auricle			1 (0.1)	1 (0.1)
Gastrointestinal tract disorders congenital NEC	1 (0.1)		1 (0.1)	2 (0.1)
Congenital inguinal hernia	1 (0.1)			1 (0.1)
Gastroschisis			1 (0.1)	1 (0.1)
Great vessel disorders congenital	2 (0.3)	2 (0.2)	2 (0.3)	6 (0.3)
Aorta hypoplasia		1 (0.1)		1 (0.1)
Coarctation of the aorta		1 (0.1)	1 (0.1)	2 (0.1)
Transposition of the great vessels	2 (0.3)		1 (0.1)	3 (0.1)
Inborn errors of bilirubin metabolism		1 (0.1)		1 (0.1)
Gilbert's syndrome		1 (0.1)		1 (0.1)
Inborn errors of carbohydrate metabolism (excl glucose)	1 (0.1)			1 (0.1)
Glucose-6-phosphate dehydrogenase deficiency	1 (0.1)			1 (0.1)
Intestinal disorders congenital		2 (0.2)		2 (0.1)

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SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Congenital intestinal malformation		1 (0.1)		1 (0.1)
Duodenal atresia		1 (0.1)		1 (0.1)
Iris and choroid disorders congenital			1 (0.1)	1 (0.1)
Choroidal coloboma			1 (0.1)	1 (0.1)
Lacrimal system disorders congenital		1 (0.1)		1 (0.1)
Dacryostenosis congenital		1 (0.1)		1 (0.1)
Laryngeal and tracheal disorders congenital	1 (0.1)		1 (0.1)	2 (0.1)
Laryngomalacia			1 (0.1)	1 (0.1)
Tracheo-oesophageal fistula	1 (0.1)			1 (0.1)
Male reproductive tract disorders congenital	12 (1.6)	14 (1.7)	8 (1.0)	34 (1.4)
Chordee	1 (0.1)		2 (0.3)	3 (0.1)
Cryptorchism	5 (0.6)	3 (0.4)	3 (0.4)	11 (0.5)
Hydrocele	5 (0.6)	6 (0.7)	2 (0.3)	13 (0.5)
Hypospadias	2 (0.3)	4 (0.5)	3 (0.4)	9 (0.4)
Phimosis		1 (0.1)		1 (0.1)
Musculoskeletal and connective tissue disorders of face, neck and jaw congenital		2 (0.2)		2 (0.1)
Branchial cyst		1 (0.1)		1 (0.1)
Cleft lip		1 (0.1)		1 (0.1)
Musculoskeletal and connective tissue disorders of limbs congenital	6 (0.8)	6 (0.7)	8 (1.0)	20 (0.8)
Congenital foot malformation		1 (0.1)	1 (0.1)	2 (0.1)
Developmental hip dysplasia	1 (0.1)		3 (0.4)	4 (0.2)
Polydactyly		1 (0.1)	1 (0.1)	2 (0.1)
Syndactyly		1 (0.1)	3 (0.4)	4 (0.2)
Talipes	5 (0.6)	3 (0.4)	1 (0.1)	9 (0.4)
Musculoskeletal and connective tissue disorders of skull congenital	1 (0.1)	7 (0.8)	2 (0.3)	10 (0.4)
Brachycephaly			1 (0.1)	1 (0.1)
Craniosynostosis	1 (0.1)			1 (0.1)
Microcephaly		1 (0.1)		1 (0.1)

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SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Plagiocephaly		5 (0.6)	1 (0.1)	6 (0.3)
Scaphocephaly		1 (0.1)	1 (0.1)	2 (0.1)
Musculoskeletal and connective tissue disorders of spine congenital	2 (0.3)	1 (0.1)		3 (0.1)
Caudal regression syndrome		1 (0.1)		1 (0.1)
Hemivertebra	1 (0.1)			1 (0.1)
Spine malformation	1 (0.1)			1 (0.1)
Musculoskeletal and connective tissue disorders of trunk congenital (excl spine)		1 (0.1)		1 (0.1)
Synostosis		1 (0.1)		1 (0.1)
Neurological disorders congenital NEC	1 (0.1)			1 (0.1)
Neurofibromatosis	1 (0.1)			1 (0.1)
Ocular disorders congenital NEC			1 (0.1)	1 (0.1)
Microphthalmos			1 (0.1)	1 (0.1)
Oral cavity disorders congenital NEC		1 (0.1)	2 (0.3)	3 (0.1)
Cleft uvula		1 (0.1)		1 (0.1)
Labial tie			2 (0.3)	2 (0.1)
Palate disorders congenital		1 (0.1)		1 (0.1)
Cleft palate		1 (0.1)		1 (0.1)
Persistent foetal circulation disorders	7 (0.9)	11 (1.3)	6 (0.8)	24 (1.0)
Newborn persistent pulmonary hypertension	1 (0.1)	1 (0.1)		2 (0.1)
Patent ductus arteriosus	6 (0.8)	10 (1.2)	6 (0.8)	22 (0.9)
Pharyngeal disorders congenital			1 (0.1)	1 (0.1)
Choanal atresia			1 (0.1)	1 (0.1)
Pulmonary and bronchial disorders congenital	2 (0.3)	2 (0.2)	1 (0.1)	5 (0.2)
Congenital pneumonia	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
Cystic fibrosis	1 (0.1)			1 (0.1)
Renal and urinary tract disorders congenital NEC		3 (0.4)		3 (0.1)
Congenital hydronephrosis		3 (0.4)		3 (0.1)
Urethral valves		1 (0.1)		1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Renal disorders congenital	4 (0.5)	4 (0.5)	4 (0.5)	12 (0.5)
Congenital cystic kidney disease	1 (0.1)			1 (0.1)
Congenital pyelocaliectasis			3 (0.4)	3 (0.1)
Ectopic kidney		1 (0.1)		1 (0.1)
Kidney duplex	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
Renal aplasia	2 (0.3)	2 (0.2)		4 (0.2)
Reproductive tract disorders congenital NEC	1 (0.1)			1 (0.1)
Congenital genital malformation	1 (0.1)			1 (0.1)
Sex chromosomal abnormalities		1 (0.1)		1 (0.1)
Fragile X syndrome		1 (0.1)		1 (0.1)
Skin and subcutaneous tissue disorders congenital NEC	3 (0.4)	4 (0.5)	4 (0.5)	11 (0.5)
Birth mark	1 (0.1)		1 (0.1)	2 (0.1)
Congenital acrochordon		1 (0.1)	2 (0.3)	3 (0.1)
Congenital melanocytic naevus			1 (0.1)	1 (0.1)
Congenital naevus	1 (0.1)	2 (0.2)		3 (0.1)
Congenital skin dimples	1 (0.1)	1 (0.1)		2 (0.1)
Sebaceous naevus			1 (0.1)	1 (0.1)
Thyroid disorders congenital			1 (0.1)	1 (0.1)
Congenital hypothyroidism			1 (0.1)	1 (0.1)
Tongue disorders congenital	7 (0.9)	10 (1.2)	11 (1.4)	28 (1.2)
Ankyloglossia congenital	7 (0.9)	10 (1.2)	11 (1.4)	28 (1.2)
Ureteric disorders congenital		1 (0.1)	1 (0.1)	2 (0.1)
Congenital ureteric anomaly			1 (0.1)	1 (0.1)
Congenital ureterocele		1 (0.1)		1 (0.1)
Vascular anomalies congenital NEC		3 (0.4)	2 (0.3)	5 (0.2)
Haemangioma congenital		3 (0.4)	2 (0.3)	5 (0.2)
Ear and labyrinth disorders		2 (0.2)	3 (0.4)	5 (0.2)
Ear disorders NEC		1 (0.1)		1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Ear disorder		1 (0.1)		1 (0.1)
Hearing losses		1 (0.1)	3 (0.4)	4 (0.2)
Deafness			2 (0.3)	2 (0.1)
Deafness neurosensory		1 (0.1)		1 (0.1)
Hypoacusis			1 (0.1)	1 (0.1)
Endocrine disorders		1 (0.1)		1 (0.1)
Adrenal gland disorders NEC		1 (0.1)		1 (0.1)
Adrenal haemorrhage		1 (0.1)		1 (0.1)
Eye disorders		2 (0.2)	5 (0.6)	7 (0.3)
Choroid and vitreous structural change, deposit and degeneration		1 (0.1)	1 (0.1)	2 (0.1)
Retinopathy of prematurity		1 (0.1)	1 (0.1)	2 (0.1)
Conjunctival and corneal bleeding and vascular disorders			1 (0.1)	1 (0.1)
Conjunctival haemorrhage			1 (0.1)	1 (0.1)
Lid, lash and lacrimal infections, irritations and inflammations			1 (0.1)	1 (0.1)
Erythema of eyelid			1 (0.1)	1 (0.1)
Ocular bleeding and vascular disorders NEC			1 (0.1)	1 (0.1)
Ocular vascular disorder			1 (0.1)	1 (0.1)
Ocular nerve and muscle disorders		1 (0.1)	1 (0.1)	2 (0.1)
Strabismus		1 (0.1)	1 (0.1)	2 (0.1)
Gastrointestinal disorders	10 (1.3)	11 (1.3)	12 (1.5)	33 (1.4)
Colitis (excl infective)	1 (0.1)		1 (0.1)	2 (0.1)
Necrotising colitis	1 (0.1)		1 (0.1)	2 (0.1)
Diarrhoea (excl infective)		1 (0.1)		1 (0.1)
Diarrhoea		1 (0.1)		1 (0.1)
Duodenal and small intestinal stenosis and obstruction	1 (0.1)			1 (0.1)
Meconium ileus	1 (0.1)			1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Gastric ulcers and perforation		1 (0.1)		1 (0.1)
Gastric ulcer		1 (0.1)		1 (0.1)
Gastrointestinal atonic and hypomotility disorders NEC	2 (0.3)	3 (0.4)	5 (0.6)	10 (0.4)
Constipation		3 (0.4)	3 (0.4)	6 (0.3)
Gastrooesophageal reflux disease	2 (0.3)		2 (0.3)	4 (0.2)
Gastrointestinal disorders NEC		1 (0.1)		1 (0.1)
Intestinal prolapse		1 (0.1)		1 (0.1)
Gastrointestinal stenosis and obstruction NEC	1 (0.1)			1 (0.1)
Intestinal stenosis	1 (0.1)			1 (0.1)
Gastrointestinal vascular malformations		1 (0.1)		1 (0.1)
Dieulafoy's vascular malformation		1 (0.1)		1 (0.1)
Inguinal hernias	1 (0.1)		3 (0.4)	4 (0.2)
Inguinal hernia	1 (0.1)		3 (0.4)	4 (0.2)
Intestinal ulcers and perforation NEC		1 (0.1)		1 (0.1)
Small intestinal perforation		1 (0.1)		1 (0.1)
Nausea and vomiting symptoms	2 (0.3)	2 (0.2)	3 (0.4)	7 (0.3)
Infantile vomiting	1 (0.1)			1 (0.1)
Regurgitation		1 (0.1)		1 (0.1)
Vomiting	1 (0.1)	1 (0.1)	3 (0.4)	5 (0.2)
Non-site specific gastrointestinal haemorrhages			1 (0.1)	1 (0.1)
Haematemesis			1 (0.1)	1 (0.1)
Oesophageal stenosis and obstruction	1 (0.1)			1 (0.1)
Oesophageal stenosis	1 (0.1)			1 (0.1)
Umbilical hernias	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
Umbilical hernia	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
General disorders and administration site conditions	4 (0.5)	9 (1.1)	10 (1.3)	23 (1.0)
Asthenic conditions		1 (0.1)	2 (0.3)	3 (0.1)
Malaise		1 (0.1)	1 (0.1)	2 (0.1)

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SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Sluggishness			1 (0.1)	1 (0.1)
Death and sudden death		1 (0.1)	1 (0.1)	2 (0.1)
Death neonatal		1 (0.1)	1 (0.1)	2 (0.1)
Febrile disorders		3 (0.4)	4 (0.5)	7 (0.3)
Fever neonatal			3 (0.4)	3 (0.1)
Pyrexia		3 (0.4)	1 (0.1)	4 (0.2)
Feelings and sensations NEC	1 (0.1)		1 (0.1)	2 (0.1)
Feeling jittery	1 (0.1)		1 (0.1)	2 (0.1)
General signs and symptoms NEC	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Ill-defined disorder		1 (0.1)		1 (0.1)
Macrosomia			1 (0.1)	1 (0.1)
Screaming	1 (0.1)			1 (0.1)
Swelling			1 (0.1)	1 (0.1)
Hernias NEC	1 (0.1)			1 (0.1)
Hernia	1 (0.1)			1 (0.1)
Mucosal findings abnormal		1 (0.1)		1 (0.1)
Polyp		1 (0.1)		1 (0.1)
Withdrawal and rebound effects	1 (0.1)	2 (0.2)		3 (0.1)
Drug withdrawal syndrome		1 (0.1)		1 (0.1)
Withdrawal syndrome	1 (0.1)	1 (0.1)		2 (0.1)
Hepatobiliary disorders	15 (1.9)	19 (2.3)	20 (2.5)	54 (2.3)
Cholestasis and jaundice	14 (1.8)	18 (2.2)	20 (2.5)	52 (2.2)
Hyperbilirubinaemia	2 (0.3)	1 (0.1)	5 (0.6)	8 (0.3)
Hyperbilirubinaemia neonatal		1 (0.1)	2 (0.3)	3 (0.1)
Jaundice	12 (1.6)	16 (1.9)	13 (1.6)	41 (1.7)
Hepatic vascular disorders		1 (0.1)		1 (0.1)
Hepatic haematoma		1 (0.1)		1 (0.1)
Hepatobiliary signs and symptoms	1 (0.1)			1 (0.1)

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SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants – FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Hepatosplenomegaly	1 (0.1)			1 (0.1)
Immune system disorders	1 (0.1)	4 (0.5)	2 (0.3)	7 (0.3)
Allergies to foods, food additives, drugs and other chemicals	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
Drug hypersensitivity	1 (0.1)			1 (0.1)
Milk allergy		2 (0.2)	1 (0.1)	3 (0.1)
Blood isoimmune reactions		2 (0.2)	1 (0.1)	3 (0.1)
ABO incompatibility		2 (0.2)		2 (0.1)
Rhesus incompatibility			1 (0.1)	1 (0.1)
Infections and infestations	43 (5.6)	74 (8.9)	58 (7.3)	175 (7.3)
Abdominal and gastrointestinal infections		2 (0.2)	1 (0.1)	3 (0.1)
Gastroenteritis		1 (0.1)	1 (0.1)	2 (0.1)
Peritonitis		1 (0.1)		1 (0.1)
Bacterial infections NEC	2 (0.3)	2 (0.2)		4 (0.2)
Bacterial sepsis	1 (0.1)			1 (0.1)
Cellulitis	1 (0.1)			1 (0.1)
Urinary tract infection bacterial		2 (0.2)		2 (0.1)
Candida infections	1 (0.1)			1 (0.1)
Oral candidiasis	1 (0.1)			1 (0.1)
Central nervous system and spinal infections	1 (0.1)			1 (0.1)
Meningitis	1 (0.1)			1 (0.1)
Ear infections			1 (0.1)	1 (0.1)
Otitis media acute			1 (0.1)	1 (0.1)
Enteroviral infections NEC		1 (0.1)	1 (0.1)	2 (0.1)
Enterovirus infection		1 (0.1)	1 (0.1)	2 (0.1)
Escherichia infections		1 (0.1)		1 (0.1)
Escherichia urinary tract infection		1 (0.1)		1 (0.1)
Eye and eyelid infections			1 (0.1)	1 (0.1)

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SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Ophthalmia neonatorum			1 (0.1)	1 (0.1)
Female reproductive tract infections	1 (0.1)		1 (0.1)	2 (0.1)
Intrauterine infection			1 (0.1)	1 (0.1)
Uterine infection	1 (0.1)			1 (0.1)
Haemophilus infections	1 (0.1)			1 (0.1)
Haemophilus bacteraemia	1 (0.1)			1 (0.1)
Herpes viral infections	1 (0.1)		1 (0.1)	2 (0.1)
Varicella	1 (0.1)		1 (0.1)	2 (0.1)
Infections NEC	6 (0.8)	7 (0.8)	10 (1.3)	23 (1.0)
Infection	5 (0.6)	1 (0.1)	3 (0.4)	9 (0.4)
Neonatal infection		5 (0.6)	5 (0.6)	10 (0.4)
Respiratory tract infection	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Infectious disorders carrier		1 (0.1)	2 (0.3)	3 (0.1)
Bacterial disease carrier		1 (0.1)	2 (0.3)	3 (0.1)
Influenza viral infections		1 (0.1)	1 (0.1)	2 (0.1)
Influenza		1 (0.1)	1 (0.1)	2 (0.1)
Lower respiratory tract and lung infections	5 (0.6)	12 (1.4)	9 (1.1)	26 (1.1)
Bronchitis			2 (0.3)	2 (0.1)
Infectious pleural effusion			1 (0.1)	1 (0.1)
Lower respiratory tract infection	1 (0.1)			1 (0.1)
Neonatal pneumonia		2 (0.2)		2 (0.1)
Pneumonia	4 (0.5)	10 (1.2)	6 (0.8)	20 (0.8)
Respiratory syncytial viral infections	6 (0.8)	11 (1.3)	6 (0.8)	23 (1.0)
Pneumonia respiratory syncytial viral		1 (0.1)		1 (0.1)
Respiratory syncytial virus bronchiolitis	1 (0.1)	3 (0.4)	1 (0.1)	5 (0.2)
Respiratory syncytial virus infection	5 (0.6)	7 (0.8)	5 (0.6)	17 (0.7)
Rotaviral infections			2 (0.3)	2 (0.1)
Rotavirus infection			2 (0.3)	2 (0.1)
Sepsis, bacteraemia, viraemia and fungaemia NEC	11 (1.4)	27 (3.3)	19 (2.4)	57 (2.4)

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SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Sepsis	7 (0.9)	8 (1.0)	8 (1.0)	23 (1.0)
Sepsis neonatal	4 (0.5)	19 (2.3)	11 (1.4)	34 (1.4)
Staphylococcal infections	2 (0.3)	1 (0.1)		3 (0.1)
Staphylococcal bacteraemia		1 (0.1)		1 (0.1)
Staphylococcal impetigo	1 (0.1)			1 (0.1)
Staphylococcal sepsis	1 (0.1)			1 (0.1)
Streptococcal infections			2 (0.3)	2 (0.1)
Beta haemolytic streptococcal infection			1 (0.1)	1 (0.1)
Streptococcal sepsis			1 (0.1)	1 (0.1)
Upper respiratory tract infections	2 (0.3)	5 (0.6)	1 (0.1)	8 (0.3)
Croup infectious	1 (0.1)			1 (0.1)
Laryngitis			1 (0.1)	1 (0.1)
Pharyngitis		1 (0.1)		1 (0.1)
Subglottic laryngitis		1 (0.1)		1 (0.1)
Upper respiratory tract infection	1 (0.1)	3 (0.4)		4 (0.2)
Urinary tract infections	3 (0.4)	3 (0.4)	2 (0.3)	8 (0.3)
Pyelonephritis	2 (0.3)	1 (0.1)	1 (0.1)	4 (0.2)
Pyelonephritis acute		1 (0.1)		1 (0.1)
Urinary tract infection	1 (0.1)	1 (0.1)		2 (0.1)
Urinary tract infection neonatal			1 (0.1)	1 (0.1)
Viral infections NEC	6 (0.8)	12 (1.4)	7 (0.9)	25 (1.0)
Bronchiolitis	1 (0.1)	9 (1.1)	7 (0.9)	17 (0.7)
Gastritis viral	1 (0.1)			1 (0.1)
Gastroenteritis viral	2 (0.3)			2 (0.1)
Meningitis viral		1 (0.1)		1 (0.1)
Viral infection	2 (0.3)			2 (0.1)
Viral rhinitis		1 (0.1)		1 (0.1)
Viral upper respiratory tract infection		1 (0.1)		1 (0.1)

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SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Injury, poisoning and procedural complications	5 (0.6)	8 (1.0)	9 (1.1)	22 (0.9)
Anaesthetic and allied procedural complications			1 (0.1)	1 (0.1)
Anaesthetic complication			1 (0.1)	1 (0.1)
Cerebral injuries NEC	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Epidural haemorrhage	1 (0.1)			1 (0.1)
Subdural haematoma			1 (0.1)	1 (0.1)
Subdural haemorrhage			1 (0.1)	1 (0.1)
Traumatic intracranial haemorrhage		1 (0.1)		1 (0.1)
Limb fractures and dislocations	2 (0.3)		4 (0.5)	6 (0.3)
Clavicle fracture			2 (0.3)	2 (0.1)
Fracture of clavicle due to birth trauma	1 (0.1)		1 (0.1)	2 (0.1)
Humerus fracture	1 (0.1)		1 (0.1)	2 (0.1)
Non-site specific injuries NEC		2 (0.2)	1 (0.1)	3 (0.1)
Fall		2 (0.2)	1 (0.1)	3 (0.1)
Non-site specific procedural complications	1 (0.1)		1 (0.1)	2 (0.1)
Incisional hernia			1 (0.1)	1 (0.1)
Shunt stenosis	1 (0.1)			1 (0.1)
Peripheral nerve injuries	1 (0.1)	2 (0.2)		3 (0.1)
Injury to brachial plexus due to birth trauma	1 (0.1)	2 (0.2)		3 (0.1)
Skin injuries NEC		2 (0.2)		2 (0.1)
Contusion		1 (0.1)		1 (0.1)
Skin abrasion		1 (0.1)		1 (0.1)
Skull fractures, facial bone fractures and dislocations		1 (0.1)	2 (0.3)	3 (0.1)
Skull fracture		1 (0.1)	2 (0.3)	3 (0.1)
Investigations	12 (1.6)	27 (3.3)	35 (4.4)	74 (3.1)
Auditory function diagnostic procedures			1 (0.1)	1 (0.1)
Otoacoustic emissions test abnormal			1 (0.1)	1 (0.1)
Bacteria identification and serology (excl mycobacteria)			1 (0.1)	1 (0.1)

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SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Streptococcus test positive			1 (0.1)	1 (0.1)
Blood gas and acid base analyses			3 (0.4)	3 (0.1)
Oxygen saturation decreased			3 (0.4)	3 (0.1)
Carbohydrate tolerance analyses (incl diabetes)	1 (0.1)		1 (0.1)	2 (0.1)
Blood glucose decreased			1 (0.1)	1 (0.1)
Blood glucose fluctuation	1 (0.1)			1 (0.1)
Cardiac auscultatory investigations	1 (0.1)		3 (0.4)	4 (0.2)
Cardiac murmur	1 (0.1)		3 (0.4)	4 (0.2)
Cardiac function diagnostic procedures	1 (0.1)			1 (0.1)
Echocardiogram	1 (0.1)			1 (0.1)
Cardiac imaging procedures			1 (0.1)	1 (0.1)
Catheterisation cardiac			1 (0.1)	1 (0.1)
Foetal and neonatal diagnostic procedures	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Foetal heart rate abnormal	1 (0.1)		2 (0.3)	3 (0.1)
Foetal monitoring abnormal		1 (0.1)		1 (0.1)
Investigations NEC			1 (0.1)	1 (0.1)
Diagnostic procedure			1 (0.1)	1 (0.1)
Liver function analyses	3 (0.4)	2 (0.2)		5 (0.2)
Blood bilirubin increased	3 (0.4)	2 (0.2)		5 (0.2)
Mineral and electrolyte analyses	1 (0.1)	1 (0.1)		2 (0.1)
Blood calcium decreased	1 (0.1)	1 (0.1)		2 (0.1)
Neurologic diagnostic procedures			1 (0.1)	1 (0.1)
Brain stem auditory evoked response abnormal			1 (0.1)	1 (0.1)
Physical examination procedures and organ system status	4 (0.5)	22 (2.7)	20 (2.5)	46 (1.9)
Apgar score low			1 (0.1)	1 (0.1)
Body temperature decreased			1 (0.1)	1 (0.1)
Medical observation	3 (0.4)	19 (2.3)	9 (1.1)	31 (1.3)
Weight decreased	1 (0.1)	3 (0.4)	9 (1.1)	13 (0.5)
Platelet analyses			1 (0.1)	1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Platelet count decreased			1 (0.1)	1 (0.1)
Protein analyses NEC		1 (0.1)		1 (0.1)
C-reactive protein increased		1 (0.1)		1 (0.1)
Red blood cell analyses			1 (0.1)	1 (0.1)
Haematocrit decreased			1 (0.1)	1 (0.1)
White blood cell analyses			1 (0.1)	1 (0.1)
White blood cell count increased			1 (0.1)	1 (0.1)
Metabolism and nutrition disorders	59 (7.6)	75 (9.1)	67 (8.4)	201 (8.4)
Appetite disorders		1 (0.1)		1 (0.1)
Decreased appetite		1 (0.1)		1 (0.1)
Calcium metabolism disorders	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
Hypocalcaemia	1 (0.1)	2 (0.2)		3 (0.1)
Neonatal hypocalcaemia			1 (0.1)	1 (0.1)
Diabetes mellitus (incl subtypes)	2 (0.3)			2 (0.1)
Diabetes mellitus	1 (0.1)			1 (0.1)
Type 1 diabetes mellitus	1 (0.1)			1 (0.1)
Fat soluble vitamin deficiencies and disorders	1 (0.1)			1 (0.1)
Vitamin D deficiency	1 (0.1)			1 (0.1)
General nutritional disorders NEC	4 (0.5)	13 (1.6)	9 (1.1)	26 (1.1)
Failure to thrive		2 (0.2)		2 (0.1)
Overfeeding of infant			1 (0.1)	1 (0.1)
Poor feeding infant	3 (0.4)	5 (0.6)	3 (0.4)	11 (0.5)
Weight gain poor	1 (0.1)	6 (0.7)	5 (0.6)	12 (0.5)
Hyperglycaemic conditions NEC		1 (0.1)		1 (0.1)
Hyperglycaemia		1 (0.1)		1 (0.1)
Hypervitaminoses NEC			1 (0.1)	1 (0.1)
Hypervitaminosis			1 (0.1)	1 (0.1)
Hypoglycaemic conditions NEC	49 (6.3)	60 (7.2)	52 (6.5)	161 (6.7)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants – FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Hyperinsulinaemic hypoglycaemia	1 (0.1)			1 (0.1)
Hypoglycaemia	13 (1.7)	15 (1.8)	16 (2.0)	44 (1.8)
Hypoglycaemia neonatal	35 (4.5)	45 (5.4)	37 (4.7)	117 (4.9)
Metabolic disorders NEC	1 (0.1)			1 (0.1)
Metabolic disorder	1 (0.1)			1 (0.1)
Mixed acid-base disorders		1 (0.1)	2 (0.3)	3 (0.1)
Acidosis		1 (0.1)	2 (0.3)	3 (0.1)
Phosphorus metabolism disorders			1 (0.1)	1 (0.1)
Hyperphosphataemia			1 (0.1)	1 (0.1)
Sodium imbalance	2 (0.3)		2 (0.3)	4 (0.2)
Hypernatraemia	1 (0.1)		2 (0.3)	3 (0.1)
Hyponatraemia	1 (0.1)			1 (0.1)
Total fluid volume decreased	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
Dehydration		1 (0.1)	1 (0.1)	2 (0.1)
Hypovolaemia	1 (0.1)			1 (0.1)
Musculoskeletal and connective tissue disorders	3 (0.4)	1 (0.1)	4 (0.5)	8 (0.3)
Epiphyseal disorders			1 (0.1)	1 (0.1)
Epiphysiolysis			1 (0.1)	1 (0.1)
Extremity deformities		1 (0.1)		1 (0.1)
Foot deformity		1 (0.1)		1 (0.1)
Joint related disorders NEC	1 (0.1)			1 (0.1)
Hypermobility syndrome	1 (0.1)			1 (0.1)
Metabolic bone disorders	1 (0.1)			1 (0.1)
Osteopenia	1 (0.1)			1 (0.1)
Muscle tone abnormalities	1 (0.1)		2 (0.3)	3 (0.1)
Hypotonia neonatal	1 (0.1)			1 (0.1)
Torticollis			2 (0.3)	2 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity			1 (0.1)	1 (0.1)
Newborn head moulding			1 (0.1)	1 (0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (0.6)	4 (0.5)	2 (0.3)	11 (0.5)
Cardiovascular neoplasms benign	3 (0.4)	2 (0.2)	2 (0.3)	7 (0.3)
Haemangioma	2 (0.3)	1 (0.1)	2 (0.3)	5 (0.2)
Infantile haemangioma	1 (0.1)	1 (0.1)		2 (0.1)
Ocular neoplasms benign		1 (0.1)		1 (0.1)
Eyelid haemangioma		1 (0.1)		1 (0.1)
Skin neoplasms benign	2 (0.3)	1 (0.1)		3 (0.1)
Haemangioma of skin	1 (0.1)	1 (0.1)		2 (0.1)
Melanocytic naevus	1 (0.1)			1 (0.1)
Nervous system disorders	7 (0.9)	12 (1.4)	14 (1.8)	33 (1.4)
Abnormal reflexes		2 (0.2)		2 (0.1)
Poor sucking reflex		2 (0.2)		2 (0.1)
Central nervous system haemorrhages and cerebrovascular accidents	1 (0.1)	1 (0.1)	5 (0.6)	7 (0.3)
Cerebral haemorrhage			1 (0.1)	1 (0.1)
Cerebral infarction	1 (0.1)			1 (0.1)
Cerebrovascular accident			1 (0.1)	1 (0.1)
Intracranial haematoma			1 (0.1)	1 (0.1)
Intraventricular haemorrhage		1 (0.1)		1 (0.1)
Intraventricular haemorrhage neonatal			2 (0.3)	2 (0.1)
Central nervous system vascular disorders NEC			2 (0.3)	2 (0.1)
Lenticulostriatal vasculopathy			2 (0.3)	2 (0.1)
Encephalopathies NEC	1 (0.1)			1 (0.1)
Periventricular leukomalacia	1 (0.1)			1 (0.1)
Generalised tonic-clonic seizures		1 (0.1)		1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Generalised tonic-clonic seizure		1 (0.1)		1 (0.1)
Hydrocephalic conditions	1 (0.1)	1 (0.1)		2 (0.1)
Hydrocephalus	1 (0.1)	1 (0.1)		2 (0.1)
Muscle tone abnormal		2 (0.2)	1 (0.1)	3 (0.1)
Hypotonia		2 (0.2)	1 (0.1)	3 (0.1)
Nervous system cysts and polyps		2 (0.2)		2 (0.1)
Cerebral cyst		2 (0.2)		2 (0.1)
Nervous system disorders NEC			3 (0.4)	3 (0.1)
Central nervous system lesion			1 (0.1)	1 (0.1)
Cerebral disorder			1 (0.1)	1 (0.1)
Psychomotor skills impaired			1 (0.1)	1 (0.1)
Neurological signs and symptoms NEC		1 (0.1)	1 (0.1)	2 (0.1)
Myoclonus		1 (0.1)		1 (0.1)
Unresponsive to stimuli			1 (0.1)	1 (0.1)
Paralysis and paresis (excl cranial nerve)	1 (0.1)			1 (0.1)
Paresis	1 (0.1)			1 (0.1)
Seizures and seizure disorders NEC	2 (0.3)	2 (0.2)	3 (0.4)	7 (0.3)
Febrile convulsion	2 (0.3)	1 (0.1)	2 (0.3)	5 (0.2)
Partial seizures	1 (0.1)			1 (0.1)
Seizure	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
Spinal cord and nerve root disorders NEC	1 (0.1)			1 (0.1)
Tethered cord syndrome	1 (0.1)			1 (0.1)
Structural brain disorders NEC		1 (0.1)		1 (0.1)
Cerebral ventricle dilatation		1 (0.1)		1 (0.1)
Pregnancy, puerperium and perinatal conditions	72 (9.3)	113 (13.6)	106 (13.3)	291 (12.1)
Amniotic fluid and cavity disorders of pregnancy NEC		1 (0.1)		1 (0.1)
Oligohydramnios		1 (0.1)		1 (0.1)
Foetal complications NEC		4 (0.5)	2 (0.3)	6 (0.3)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Foetal cardiac disorder			1 (0.1)	1 (0.1)
Foetal distress syndrome		4 (0.5)	1 (0.1)	5 (0.2)
Foetal growth complications		1 (0.1)	1 (0.1)	2 (0.1)
Foetal growth restriction			1 (0.1)	1 (0.1)
Foetal macrosomia		1 (0.1)		1 (0.1)
Foetal position and presentation abnormalities	2 (0.3)	4 (0.5)		6 (0.3)
Foetal malposition		1 (0.1)		1 (0.1)
Shoulder dystocia	2 (0.3)	3 (0.4)		5 (0.2)
Gestational age and weight conditions	52 (6.7)	71 (8.6)	69 (8.7)	192 (8.0)
Large for dates baby	4 (0.5)	2 (0.2)	2 (0.3)	8 (0.3)
Low birth weight baby			2 (0.3)	2 (0.1)
Poor weight gain neonatal		1 (0.1)		1 (0.1)
Premature baby	48 (6.2)	68 (8.2)	62 (7.8)	178 (7.4)
Small for dates baby	1 (0.1)	1 (0.1)		2 (0.1)
Weight decrease neonatal			4 (0.5)	4 (0.2)
Haemorrhagic complications of pregnancy			1 (0.1)	1 (0.1)
Premature separation of placenta			1 (0.1)	1 (0.1)
Hypertension associated disorders of pregnancy			1 (0.1)	1 (0.1)
Gestational hypertension			1 (0.1)	1 (0.1)
Labour onset and length abnormalities	4 (0.5)	7 (0.8)	1 (0.1)	12 (0.5)
Premature delivery	4 (0.5)	6 (0.7)	1 (0.1)	11 (0.5)
Premature labour		1 (0.1)		1 (0.1)
Maternal complications of delivery NEC			1 (0.1)	1 (0.1)
Breech delivery			1 (0.1)	1 (0.1)
Neonatal disorders due to birth trauma (excl intracranial haemorrhages)	1 (0.1)	2 (0.2)		3 (0.1)
Birth trauma		1 (0.1)		1 (0.1)
Caput succedaneum		1 (0.1)		1 (0.1)
Cephalhaematoma	1 (0.1)			1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Neonatal hepatobiliary disorders	18 (2.3)	39 (4.7)	34 (4.3)	91 (3.8)
Jaundice neonatal	18 (2.3)	39 (4.7)	34 (4.3)	91 (3.8)
Neonatal metabolic and endocrine disorders	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
Hypothermia neonatal	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
Newborn complications NEC			2 (0.3)	2 (0.1)
Anaesthetic complication neonatal			1 (0.1)	1 (0.1)
Neonatal disorder			1 (0.1)	1 (0.1)
Umbilical cord complications	1 (0.1)			1 (0.1)
Umbilical cord abnormality	1 (0.1)			1 (0.1)
Psychiatric disorders	2 (0.3)	4 (0.5)	1 (0.1)	7 (0.3)
Eating disorders NEC	2 (0.3)	4 (0.5)		6 (0.3)
Anorexia nervosa		1 (0.1)		1 (0.1)
Eating disorder		1 (0.1)		1 (0.1)
Selective eating disorder	2 (0.3)	2 (0.2)		4 (0.2)
Mood disorders NEC			1 (0.1)	1 (0.1)
Apathy			1 (0.1)	1 (0.1)
Renal and urinary disorders	2 (0.3)	6 (0.7)	2 (0.3)	10 (0.4)
Bladder reflux conditions		1 (0.1)		1 (0.1)
Vesicoureteric reflux		1 (0.1)		1 (0.1)
Myoneurogenic bladder disorders		1 (0.1)		1 (0.1)
Neurogenic bladder		1 (0.1)		1 (0.1)
Renal failure and impairment	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
Renal failure			1 (0.1)	1 (0.1)
Renal failure neonatal	1 (0.1)	2 (0.2)		3 (0.1)
Renal obstructive disorders			1 (0.1)	1 (0.1)
Hydronephrosis			1 (0.1)	1 (0.1)
Renal structural abnormalities and trauma	1 (0.1)	2 (0.2)		3 (0.1)

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SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants – FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Pyelocaliectasis	1 (0.1)	2 (0.2)		3 (0.1)
Renal vascular and ischaemic conditions	1 (0.1)			1 (0.1)
Renal vein thrombosis	1 (0.1)			1 (0.1)
Ureteric disorders NEC		1 (0.1)		1 (0.1)
Hydroureter		1 (0.1)		1 (0.1)
Reproductive system and breast disorders			1 (0.1)	1 (0.1)
Vulvovaginal disorders NEC			1 (0.1)	1 (0.1)
Vulvovaginal disorder			1 (0.1)	1 (0.1)
Respiratory, thoracic and mediastinal disorders	67 (8.7)	98 (11.8)	98 (12.3)	263 (11.0)
Breathing abnormalities	16 (2.1)	27 (3.3)	26 (3.3)	69 (2.9)
Apnoea	2 (0.3)	1 (0.1)	2 (0.3)	5 (0.2)
Apnoeic attack		1 (0.1)		1 (0.1)
Dyspnoea	2 (0.3)	1 (0.1)	2 (0.3)	5 (0.2)
Respiration abnormal	1 (0.1)			1 (0.1)
Respiratory arrest		1 (0.1)		1 (0.1)
Respiratory distress	11 (1.4)	20 (2.4)	20 (2.5)	51 (2.1)
Tachypnoea		3 (0.4)	2 (0.3)	5 (0.2)
Bronchospasm and obstruction	3 (0.4)	2 (0.2)		5 (0.2)
Asthma	3 (0.4)	2 (0.2)		5 (0.2)
Conditions associated with abnormal gas exchange	3 (0.4)	6 (0.7)	5 (0.6)	14 (0.6)
Asphyxia	3 (0.4)	5 (0.6)	4 (0.5)	12 (0.5)
Hypoxia		1 (0.1)		1 (0.1)
Respiratory acidosis			1 (0.1)	1 (0.1)
Laryngeal spasm, oedema and obstruction		1 (0.1)		1 (0.1)
Stridor		1 (0.1)		1 (0.1)
Lower respiratory tract signs and symptoms			1 (0.1)	1 (0.1)
Pulmonary haemorrhage			1 (0.1)	1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Neonatal hypoxic conditions	29 (3.8)	47 (5.7)	49 (6.2)	125 (5.2)
Cyanosis neonatal			1 (0.1)	1 (0.1)
Infantile apnoea		1 (0.1)	4 (0.5)	5 (0.2)
Neonatal asphyxia		5 (0.6)		5 (0.2)
Neonatal hypoxia	1 (0.1)			1 (0.1)
Neonatal respiratory arrest		1 (0.1)		1 (0.1)
Neonatal respiratory distress	11 (1.4)	12 (1.4)	15 (1.9)	38 (1.6)
Neonatal respiratory distress syndrome	17 (2.2)	28 (3.4)	33 (4.2)	78 (3.3)
Newborn respiratory disorders NEC	17 (2.2)	20 (2.4)	14 (1.8)	51 (2.1)
Bronchopulmonary dysplasia	1 (0.1)	2 (0.2)		3 (0.1)
Neonatal aspiration	1 (0.1)			1 (0.1)
Neonatal tachypnoea	4 (0.5)	2 (0.2)	1 (0.1)	7 (0.3)
Respiratory disorder neonatal	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
Transient tachypnoea of the newborn	10 (1.3)	15 (1.8)	12 (1.5)	37 (1.5)
Parenchymal lung disorders NEC	1 (0.1)			1 (0.1)
Atelectasis	1 (0.1)			1 (0.1)
Pharyngeal disorders (excl infections and neoplasms)			1 (0.1)	1 (0.1)
Pharyngeal erythema			1 (0.1)	1 (0.1)
Tonsillar hypertrophy			1 (0.1)	1 (0.1)
Pneumothorax and pleural effusions NEC	2 (0.3)	3 (0.4)	2 (0.3)	7 (0.3)
Pneumothorax	2 (0.3)	3 (0.4)	2 (0.3)	7 (0.3)
Pulmonary hypertensions	1 (0.1)	1 (0.1)		2 (0.1)
Pulmonary arterial hypertension	1 (0.1)			1 (0.1)
Pulmonary hypertension		1 (0.1)		1 (0.1)
Pulmonary oedemas		1 (0.1)		1 (0.1)
Acute respiratory distress syndrome		1 (0.1)		1 (0.1)
Respiratory failures (excl neonatal)			1 (0.1)	1 (0.1)
Respiratory failure			1 (0.1)	1 (0.1)
Respiratory tract disorders NEC		1 (0.1)	1 (0.1)	2 (0.1)

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SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

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Respiratory disorder		1 (0.1)	1 (0.1)	2 (0.1)
Upper respiratory tract signs and symptoms	1 (0.1)	1 (0.1)		2 (0.1)
Catarrh	1 (0.1)	1 (0.1)		2 (0.1)
Vascular pulmonary disorders NEC			1 (0.1)	1 (0.1)
Pulmonary vascular disorder			1 (0.1)	1 (0.1)
Skin and subcutaneous tissue disorders	2 (0.3)		2 (0.3)	4 (0.2)
Erythemas	1 (0.1)			1 (0.1)
Umbilical erythema	1 (0.1)			1 (0.1)
Rashes, eruptions and exanthems NEC	1 (0.1)			1 (0.1)
Rash maculo-papular	1 (0.1)			1 (0.1)
Skin vasomotor conditions			2 (0.3)	2 (0.1)
Livedo reticularis			2 (0.3)	2 (0.1)
Social circumstances		3 (0.4)		3 (0.1)
Housing circumstances		1 (0.1)		1 (0.1)
Social stay hospitalisation		1 (0.1)		1 (0.1)
Social issues NEC		2 (0.2)		2 (0.1)
Disease risk factor		2 (0.2)		2 (0.1)
Surgical and medical procedures	6 (0.8)	4 (0.5)	2 (0.3)	12 (0.5)
Arterial therapeutic procedures (excl aortic)	1 (0.1)	2 (0.2)		3 (0.1)
Patent ductus arteriosus repair		2 (0.2)		2 (0.1)
Pulmonary artery banding	1 (0.1)			1 (0.1)
Bladder therapeutic procedures		1 (0.1)		1 (0.1)
Cystostomy		1 (0.1)		1 (0.1)
Cerebrospinal fluid therapeutic procedures	1 (0.1)			1 (0.1)
Ventriculo-peritoneal shunt	1 (0.1)			1 (0.1)
Chest wall and mediastinal therapeutic procedures		1 (0.1)		1 (0.1)

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MedDRA version - 22.1.

SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants – FAS_FOETUS

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Thoracotomy		1 (0.1)		1 (0.1)
Congenital cardiovascular anomaly therapeutic procedures	1 (0.1)	1 (0.1)		2 (0.1)
Systemic-pulmonary artery shunt	1 (0.1)			1 (0.1)
Ventricular septal defect repair		1 (0.1)		1 (0.1)
Gastric therapeutic procedures		1 (0.1)		1 (0.1)
Gastrostomy		1 (0.1)		1 (0.1)
Hernia repairs			1 (0.1)	1 (0.1)
Inguinal hernia repair			1 (0.1)	1 (0.1)
Penile therapeutic procedures	2 (0.3)			2 (0.1)
Circumcision	1 (0.1)			1 (0.1)
Penile operation	1 (0.1)			1 (0.1)
Peripheral nerve therapeutic procedures	1 (0.1)			1 (0.1)
Peripheral nerve operation	1 (0.1)			1 (0.1)
Renal therapeutic procedures		1 (0.1)		1 (0.1)
Nephrectomy		1 (0.1)		1 (0.1)
Therapeutic procedures NEC			1 (0.1)	1 (0.1)
Hospitalisation			1 (0.1)	1 (0.1)
Tracheal therapeutic procedures		1 (0.1)		1 (0.1)
Tracheostomy		1 (0.1)		1 (0.1)
Vascular therapeutic procedures NEC	1 (0.1)			1 (0.1)
Cavopulmonary anastomosis	1 (0.1)			1 (0.1)
Vascular disorders	4 (0.5)	2 (0.2)	4 (0.5)	10 (0.4)
Aortic necrosis and vascular insufficiency	2 (0.3)			2 (0.1)
Aortic stenosis	2 (0.3)			2 (0.1)
Blood pressure disorders NEC	1 (0.1)			1 (0.1)
Blood pressure fluctuation	1 (0.1)			1 (0.1)
Circulatory collapse and shock		1 (0.1)		1 (0.1)
Circulatory collapse		1 (0.1)		1 (0.1)

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SAE categorised by System Organ Class, High level term and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class High Level Term Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Haemorrhages NEC			4 (0.5)	4 (0.2)
Haematoma			1 (0.1)	1 (0.1)
Haemorrhage neonatal			1 (0.1)	1 (0.1)
Subgaleal haematoma			2 (0.3)	2 (0.1)
Site specific vascular disorders NEC	1 (0.1)			1 (0.1)
Aortic disorder	1 (0.1)			1 (0.1)
Vascular hypertensive disorders NEC		1 (0.1)		1 (0.1)
Hypertension neonatal		1 (0.1)		1 (0.1)

N: Number of patients with one or more events, %: percentage of patients with one or more events
MedDRA version - 22.1.

14.1.52 ADR categorised by System Organ Class and Preferred Term among mothers– FAS_MOTHER

System Organ Class Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Total number of patients	764	828	781	2373
Total number of patients with events	64 (8.4)	92 (11.1)	85 (10.9)	241 (10.2)
Blood and lymphatic system disorders	1 (0.1)			1 (0.1)
Splenic haematoma	1 (0.1)			1 (0.1)
Cardiac disorders		1 (0.1)		1 (0.1)
Palpitations		1 (0.1)		1 (0.1)
Eye disorders			2 (0.3)	2 (0.1)
Diabetic retinopathy			1 (0.1)	1 (0.1)
Vision blurred			1 (0.1)	1 (0.1)
Gastrointestinal disorders		2 (0.2)	2 (0.3)	4 (0.2)
Vomiting		2 (0.2)	2 (0.3)	4 (0.2)
General disorders and administration site conditions	2 (0.3)	1 (0.1)	4 (0.5)	7 (0.3)
Injection site eczema	1 (0.1)			1 (0.1)
Injection site erythema			1 (0.1)	1 (0.1)
Injection site oedema		1 (0.1)		1 (0.1)
Injection site pain	1 (0.1)		1 (0.1)	2 (0.1)
Macrosomia			1 (0.1)	1 (0.1)
Malaise			1 (0.1)	1 (0.1)
Hepatobiliary disorders	1 (0.1)			1 (0.1)
Hepatic haematoma	1 (0.1)			1 (0.1)

N: Number of patients with one or more events, %: percentage of patients with one or more events, ADR: Adverse drug reaction
MedDRA version - 22.1.

ADR categorised by System Organ Class and Preferred Term among mothers- FAS_MOTHER

System Organ Class Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Infections and infestations	1 (0.1)		2 (0.3)	3 (0.1)
Dermatophytosis			1 (0.1)	1 (0.1)
Herpes simplex otitis externa	1 (0.1)			1 (0.1)
Upper respiratory tract infection			1 (0.1)	1 (0.1)
Injury, poisoning and procedural complications	1 (0.1)			1 (0.1)
Femoral neck fracture	1 (0.1)			1 (0.1)
Foot fracture	1 (0.1)			1 (0.1)
Hand fracture	1 (0.1)			1 (0.1)
Rib fracture	1 (0.1)			1 (0.1)
Investigations	2 (0.3)	2 (0.2)	3 (0.4)	7 (0.3)
Blood glucose fluctuation	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Blood ketone body present		1 (0.1)		1 (0.1)
Blood pressure increased	1 (0.1)			1 (0.1)
Urine ketone body present			1 (0.1)	1 (0.1)
Metabolism and nutrition disorders	54 (7.1)	80 (9.7)	70 (9.0)	204 (8.6)
Decreased insulin requirement	1 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)
Diabetes mellitus			1 (0.1)	1 (0.1)
Diabetes mellitus inadequate control	3 (0.4)	14 (1.7)	17 (2.2)	34 (1.4)
Diabetic ketoacidosis	4 (0.5)		3 (0.4)	7 (0.3)
Diabetic metabolic decompensation			1 (0.1)	1 (0.1)
Hyperglycaemia	1 (0.1)	2 (0.2)	1 (0.1)	4 (0.2)
Hypoglycaemia	48 (6.3)	69 (8.3)	56 (7.2)	173 (7.3)
Hypoglycaemia unawareness	1 (0.1)			1 (0.1)
Ketosis		1 (0.1)		1 (0.1)
Nervous system disorders	1 (0.1)	3 (0.4)	5 (0.6)	9 (0.4)

N: Number of patients with one or more events, %: percentage of patients with one or more events, ADR: Adverse drug reaction
MedDRA version - 22.1.

ADR categorised by System Organ Class and Preferred Term among mothers- FAS_MOTHER

System Organ Class Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Headache		1 (0.1)	1 (0.1)	2 (0.1)
Hypoaesthesia			1 (0.1)	1 (0.1)
Hypoglycaemic coma			1 (0.1)	1 (0.1)
Hypoglycaemic seizure		1 (0.1)	1 (0.1)	2 (0.1)
Hypoglycaemic unconsciousness	1 (0.1)	1 (0.1)	2 (0.3)	4 (0.2)
Tremor			1 (0.1)	1 (0.1)
Pregnancy, puerperium and perinatal conditions	2 (0.3)	4 (0.5)	9 (1.2)	15 (0.6)
Abortion		1 (0.1)		1 (0.1)
Foetal disorder			2 (0.3)	2 (0.1)
Foetal macrosomia	2 (0.3)		4 (0.5)	6 (0.3)
HELLP syndrome		1 (0.1)		1 (0.1)
Large for dates baby			2 (0.3)	2 (0.1)
Polyhydramnios			1 (0.1)	1 (0.1)
Pre-eclampsia		2 (0.2)	2 (0.3)	4 (0.2)
Renal and urinary disorders	1 (0.1)		1 (0.1)	2 (0.1)
Ketonuria			1 (0.1)	1 (0.1)
Polyuria	1 (0.1)			1 (0.1)
Reproductive system and breast disorders			1 (0.1)	1 (0.1)
Coital bleeding			1 (0.1)	1 (0.1)
Skin and subcutaneous tissue disorders	1 (0.1)	3 (0.4)		4 (0.2)
Lipodystrophy acquired		1 (0.1)		1 (0.1)
Lipohypertrophy	1 (0.1)	1 (0.1)		2 (0.1)
Rash		1 (0.1)		1 (0.1)
Surgical and medical procedures		1 (0.1)	3 (0.4)	4 (0.2)

N: Number of patients with one or more events, %: percentage of patients with one or more events, ADR: Adverse drug reaction
MedDRA version - 22.1.

ADR categorised by System Organ Class and Preferred Term among mothers- FAS_MOTHER

System Organ Class Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Diabetes mellitus management		1 (0.1)		1 (0.1)
Labour induction			3 (0.4)	3 (0.1)
Vascular disorders		1 (0.1)		1 (0.1)
Hypertension		1 (0.1)		1 (0.1)

N: Number of patients with one or more events, %: percentage of patients with one or more events, ADR: Adverse drug reaction
MedDRA version - 22.1.

14.1.53 ADR categorised by System Organ Class and Preferred Term among foetus/infants – FAS_FOETUS

System Organ Class Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Total number of patients	773	828	795	2396
Total number of patients with events	26 (3.4)	24 (2.9)	33 (4.2)	83 (3.5)
Congenital, familial and genetic disorders	1 (0.1)	1 (0.1)		2 (0.1)
Cleft palate		1 (0.1)		1 (0.1)
Patent ductus arteriosus	1 (0.1)			1 (0.1)
General disorders and administration site conditions			3 (0.4)	3 (0.1)
Macrosomia			3 (0.4)	3 (0.1)
Infections and infestations		1 (0.1)		1 (0.1)
Oral fungal infection		1 (0.1)		1 (0.1)
Injury, poisoning and procedural complications			1 (0.1)	1 (0.1)
Skull fracture			1 (0.1)	1 (0.1)
Metabolism and nutrition disorders	24 (3.1)	21 (2.5)	29 (3.6)	74 (3.1)
Hyperinsulinaemic hypoglycaemia	1 (0.1)			1 (0.1)
Hypoglycaemia	7 (0.9)	3 (0.4)	7 (0.9)	17 (0.7)
Hypoglycaemia neonatal	16 (2.1)	18 (2.2)	22 (2.8)	56 (2.3)
Pregnancy, puerperium and perinatal conditions	2 (0.3)		3 (0.4)	5 (0.2)
Jaundice neonatal	1 (0.1)			1 (0.1)
Large for dates baby	1 (0.1)			1 (0.1)
Premature baby			3 (0.4)	3 (0.1)
Respiratory, thoracic and mediastinal disorders	3 (0.4)	1 (0.1)	1 (0.1)	5 (0.2)

N: Number of patients with one or more events, %: percentage of patients with one or more events, ADR: Adverse drug reaction
MedDRA version - 22.1.

ADR categorised by System Organ Class and Preferred Term among foetus/infants - FAS_FOETUS

System Organ Class Preferred Term	Insulin detemir N (%)	Other basal insulin N (%)	No basal insulin N (%)	Total N (%)
Neonatal respiratory distress syndrome			1 (0.1)	1 (0.1)
Respiratory distress	2 (0.3)	1 (0.1)		3 (0.1)
Tachypnoea	1 (0.1)			1 (0.1)

N: Number of patients with one or more events, %: percentage of patients with one or more events, ADR: Adverse drug reaction
MedDRA version - 22.1.

14.1.54 Changes of major congenital malformations by basal insulin treatment group at enrolment before and after propensity score matching - summary - INFANT analysis set

	Before propensity score matching (N=1268)				After propensity score matching (N=736)			
	Insulin Detemir (N=638)		Other Basal Insulin (N=630)		Insulin Detemir (N=368)		Other Basal Insulin (N=368)	
Changes of major congenital malformation								
n	622		609		353		355	
No change	7	(1.1)	10	(1.6)	5	(1.4)	6	(1.7)
Progression	2	(0.3)			2	(0.6)		
Regression	2	(0.3)	5	(0.8)	2	(0.6)	4	(1.1)
No major congenital malformation	611	(98.2)	594	(97.5)	344	(97.5)	345	(97.2)

N: Number of patients, SD: Standard deviation
Percentages are based on total number of patients in the analysis set with information.

nis-primary/nn304-4016/20200312_nsr_er
10AUG2020:08:37:25 - t_maj_conj_mal.sas/t_maj_conj_mal.txt

14.1.55 SAE - basal insulin treatment group at enrolment - summary – FAS_MOTHER - FAS_FOETUS

Label	Insulin detemir N(%)	Other basal insulin N(%)	No basal insulin N(%)	Total N(%)
Foetus				
	773	828	795	2396
	391(50.58)	576(69.57)	563(70.82)	1530(63.86)
Mother				
	764	828	781	2373
	431(56.41)	577(69.69)	656(83.99)	1664(70.12)

nis-primary/nn304-4016/20200312_nsr_er
10AUG2020:08:37:37 - t_sae/t_sae_total.txt

14.1.56 ADR - basal insulin treatment group at enrolment - summary – FAS_MOTHER - FAS_FOETUS

Label	Insulin detemir N(%)	Other basal insulin N(%)	No basal insulin N(%)	Total N(%)
Foetus	773	828	795	2396
	30(3.88)	24(2.90)	37(4.65)	91(3.80)
Mother	764	828	781	2373
	67(8.77)	98(11.84)	102(13.06)	267(11.25)

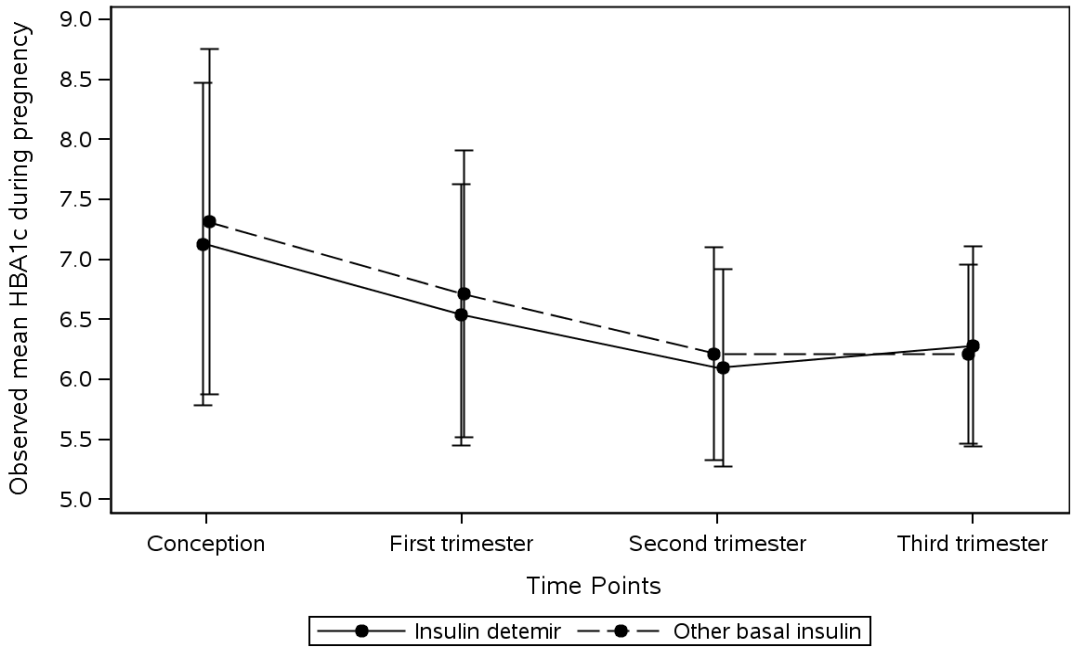
14.1.57 Subject discontinuation by delivery status - FAS MOTHER set

	Delivery	Reason	count
Total			164
	No	ADVERSE EVENT	1
	No	LOST TO FOLLOW-UP	14
	Yes	LOST TO FOLLOW-UP	119
	Yes	OTHER	12
	No	WITHDRAWAL BY SUBJECT	11
	Yes	WITHDRAWAL BY SUBJECT	7

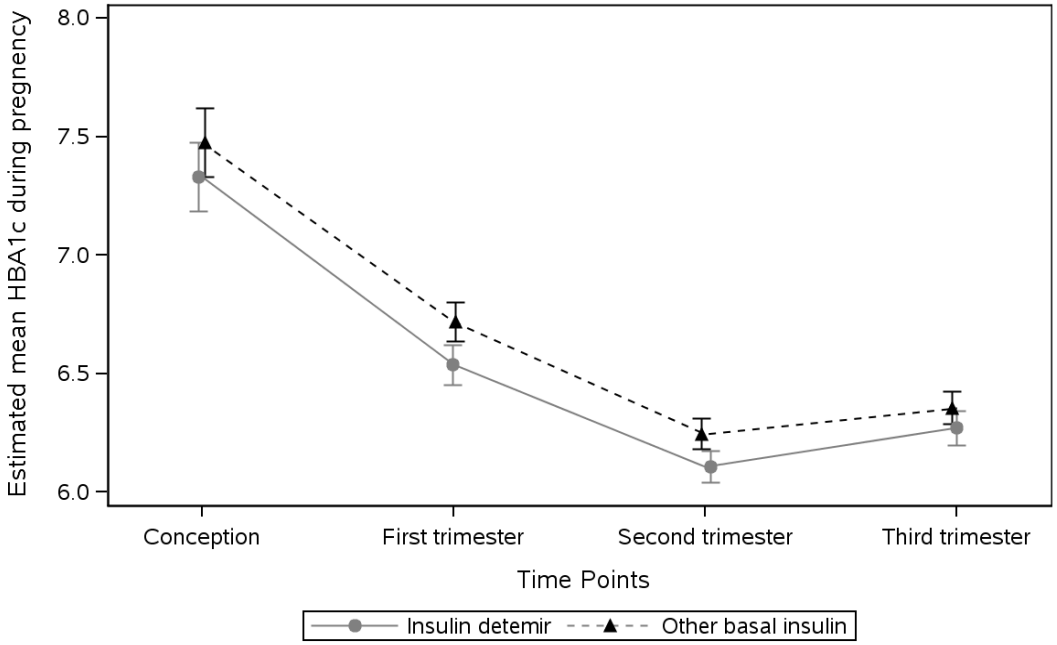
nis-primary/nn304-4016/20200312_nsr_er
10AUG2020:08:37:13 - t_disc_by_del/t_disc_by_del.txt

14.2 Efficacy data

14.2.1 Observed HbA1c during pregnancy by basal insulin treatment group at enrolment - plot (Mean +- SD) - MOTHER analysis set



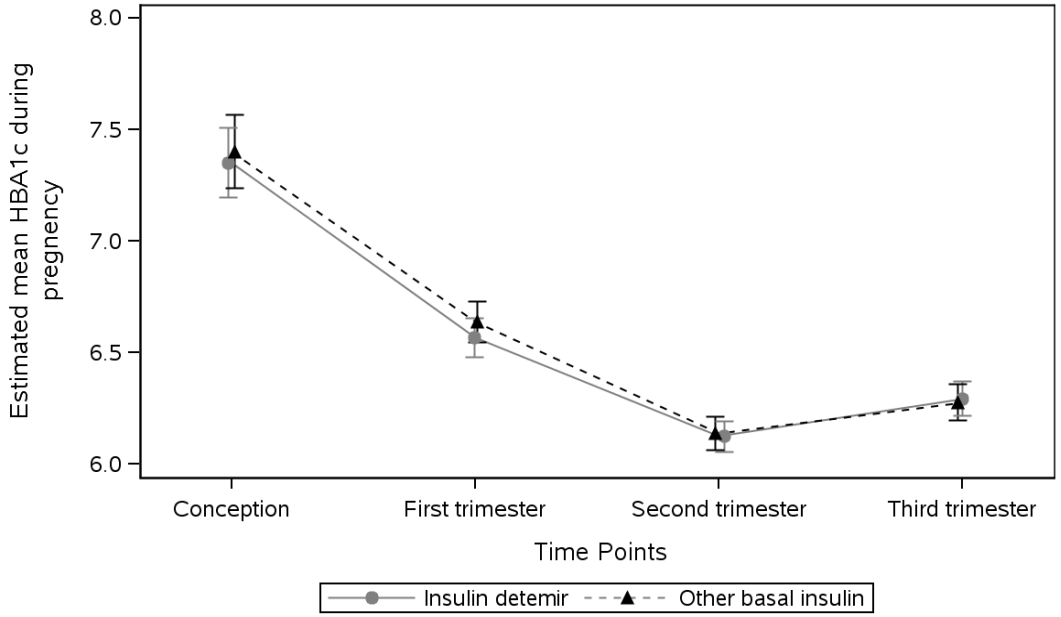
14.2.2 Estimated HbA1c during pregnancy by basal insulin treatment group at enrolment - crude - plot - MOTHER analysis set



The response is analysed using a linear mixed model for repeated measurements with women as random effect, fixed factor (time)and interaction term (time * basal insulin treatment group).
Time have the values as start of pregnancy, end of first trimester, end of second trimester and end of third trimester.

nis-primary/nn304-4016/20200312_nsr_er
10AUG2020:08:37:11 - f_est_hba1c_preg.sas/f_est_crude_hba1c_preg.png

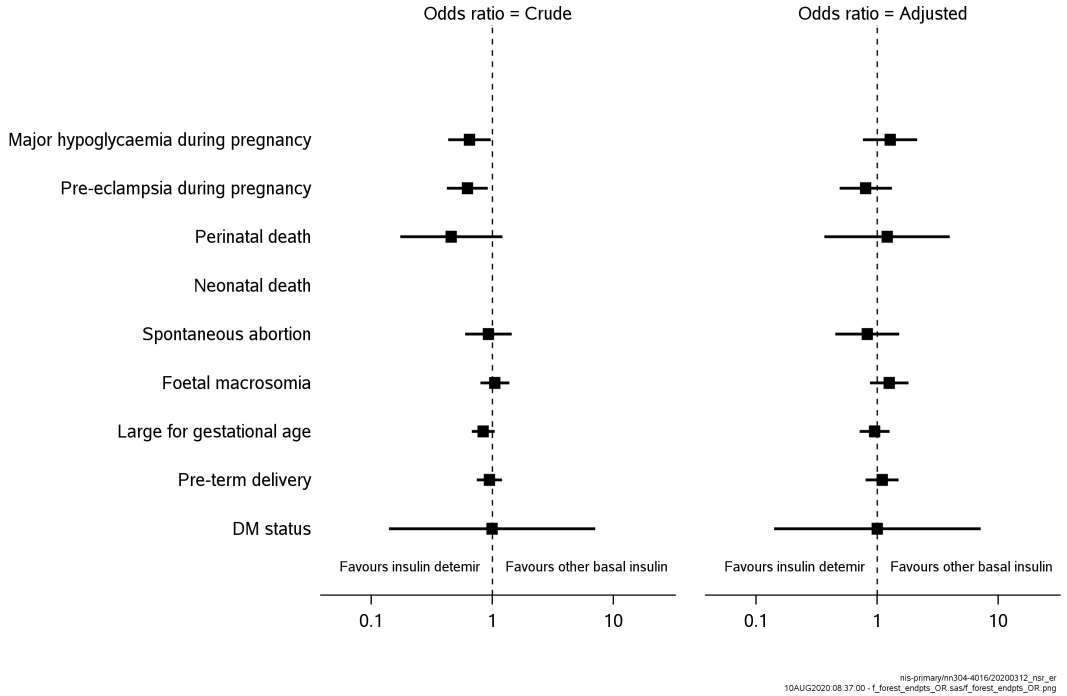
14.2.3 Estimated HbA1c during pregnancy by basal insulin treatment group at enrolment - adjusted plot - MOTHER analysis set



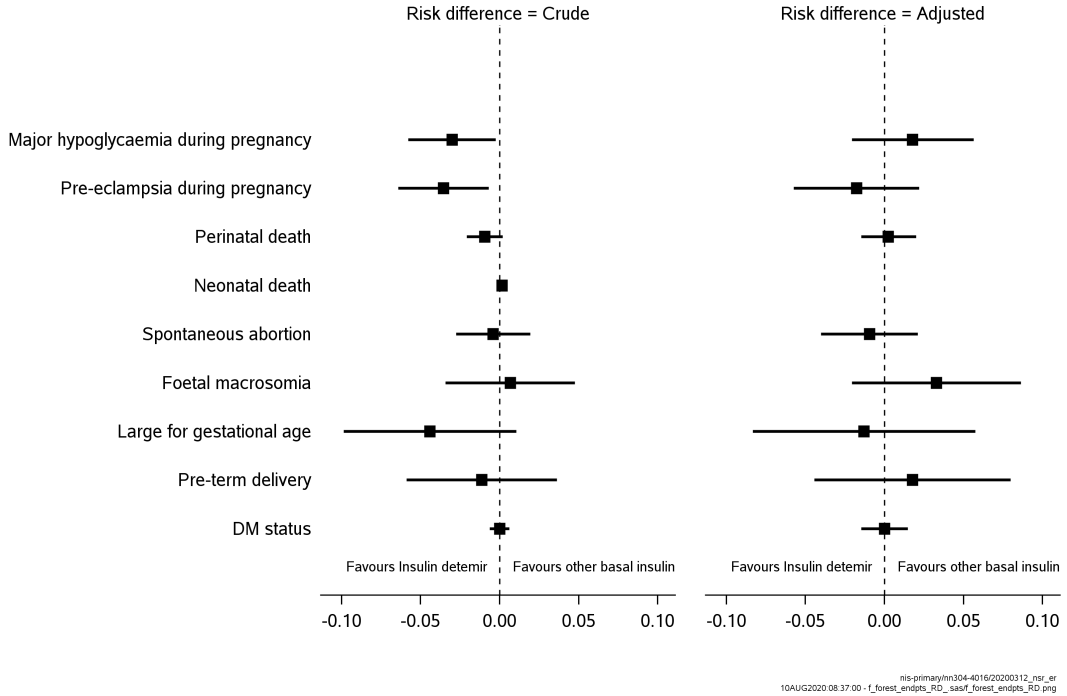
The response is analysed using a linear mixed model for repeated measurements with women as random effect, fixed factors (country, age, gestational week, type of diabetes, duration of DM, history of diabetes complications, history of foetal pregnancy complications, BMI, tobacco use, alcohol, education, bolus insulin, OAD and time) and interaction term (time * basal insulin treatment group).
Time have the values as start of pregnancy, end of first trimester, end of second trimester and end of third trimester.

nis-primary/nn304-4016/20200312_nsr_er
10AUG2020:08:37:04 - f_est_hba1c_preg.sas/f_est_adj_hba1c_preg.png

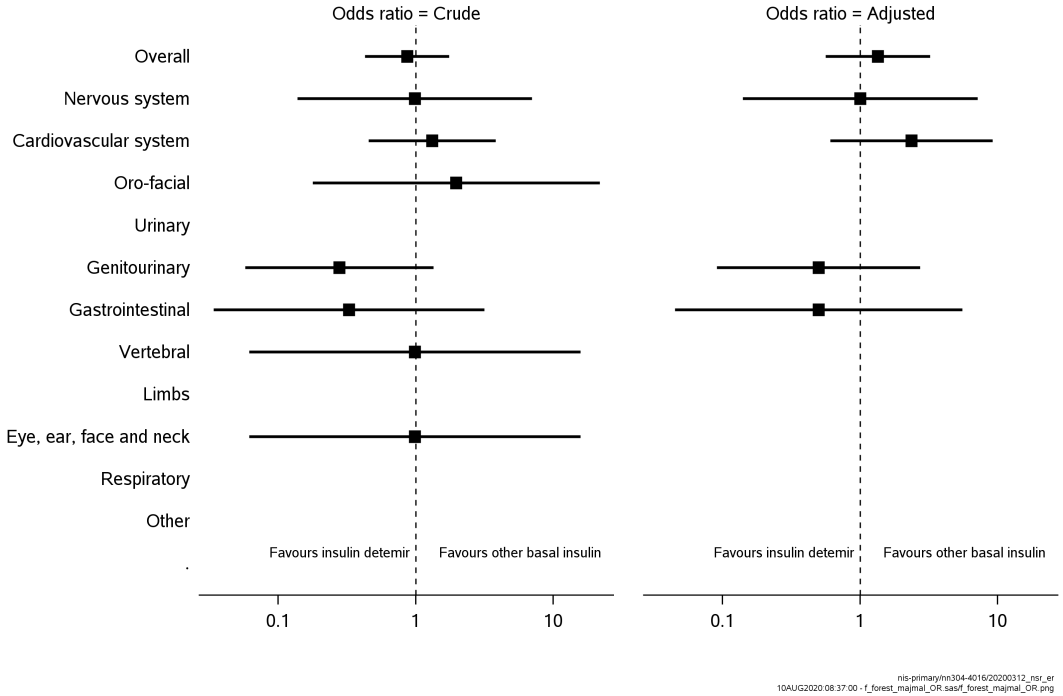
14.2.4 Odds ratio of secondary endpoints among mothers/ foetus of mothers/ liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – forest plot



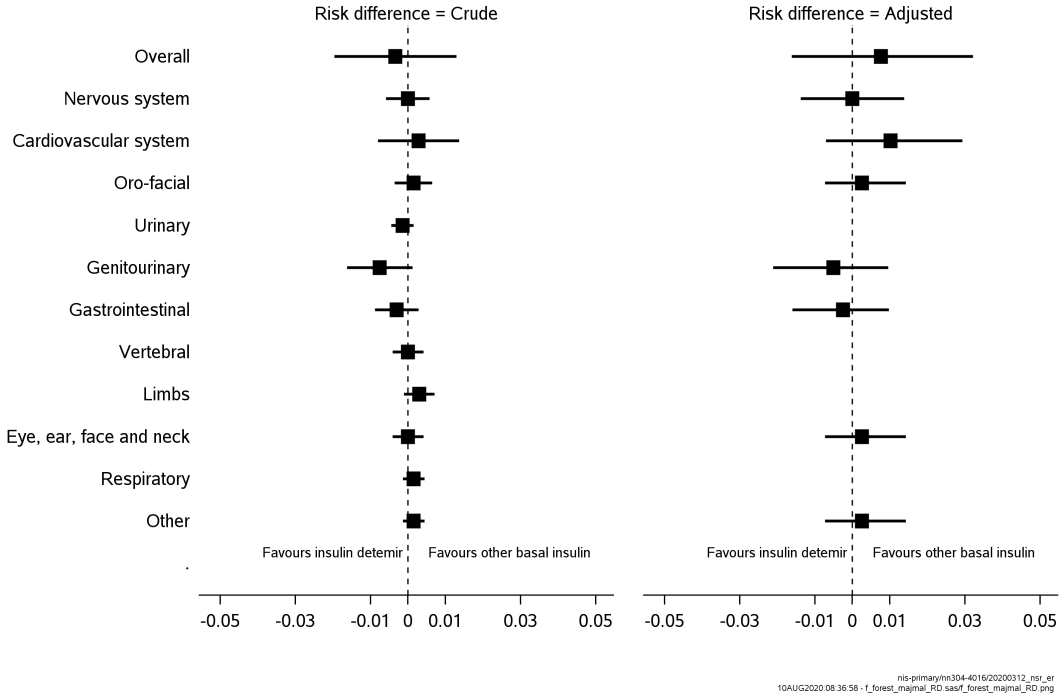
14.2.5 Risk difference of secondary endpoints among mothers/ foetus of mothers/ liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins – forest plot



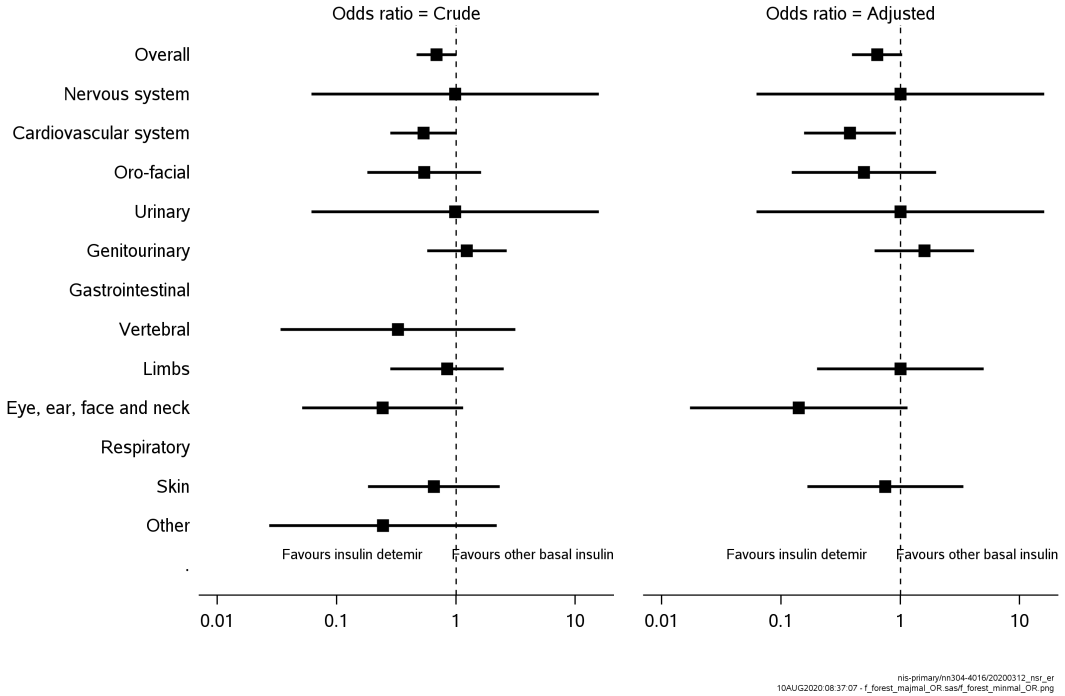
14.2.6 Odds ratio of major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ -forest plot – LIVEBORN



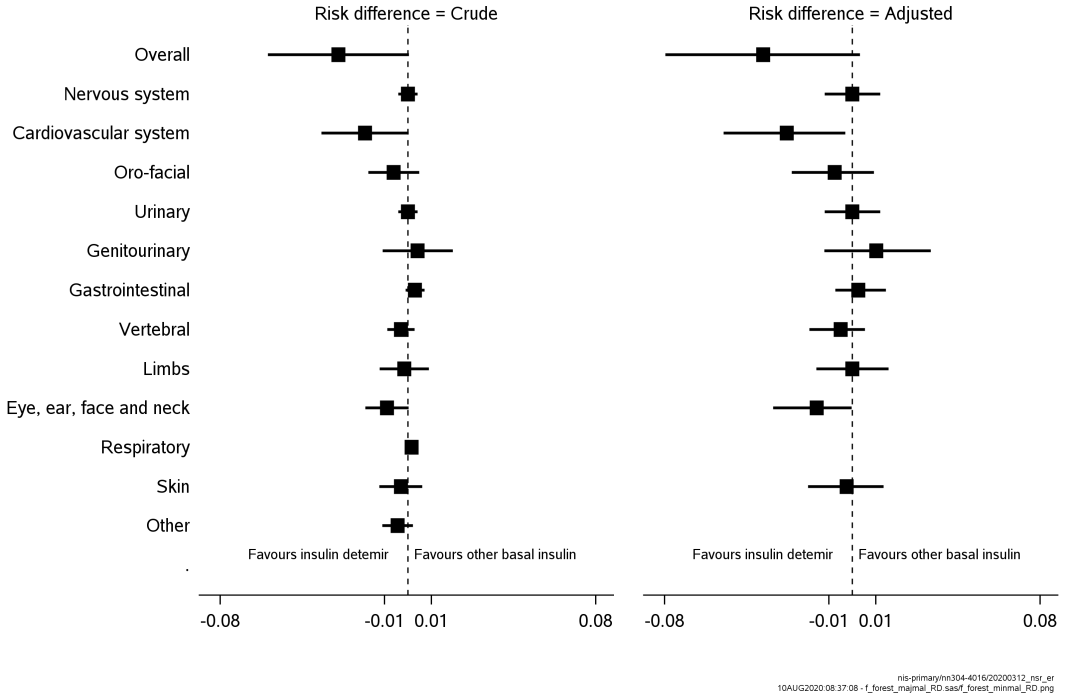
14.2.7 Risk difference of major congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ -forest plot – LIVEBORN



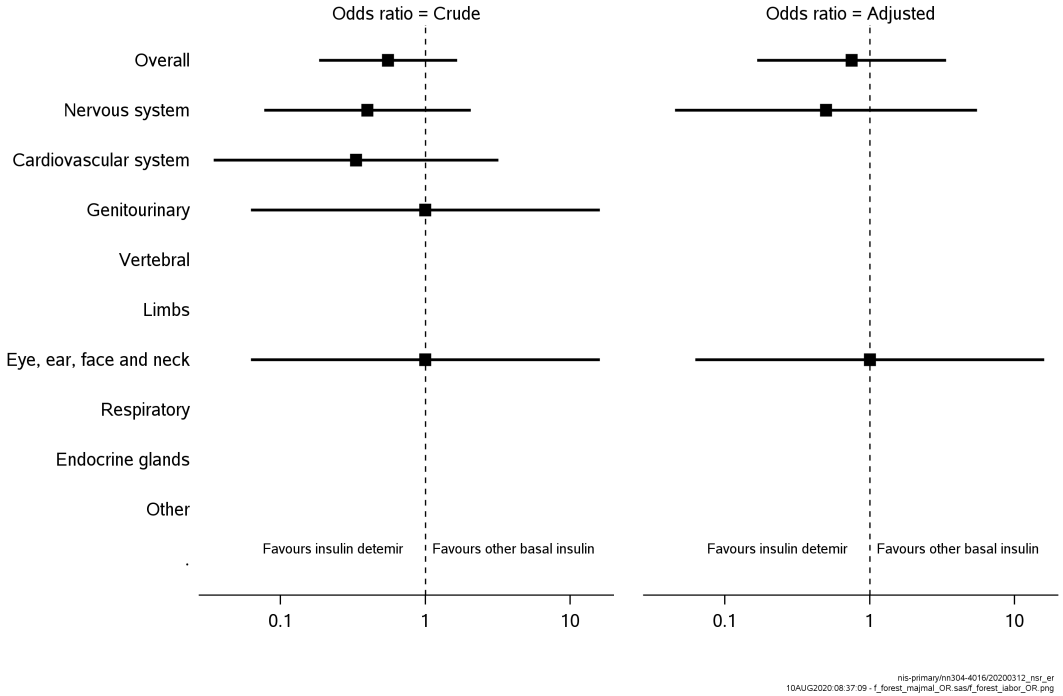
14.2.8 Odds ratio of minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ -forest plot – LIVEBORN



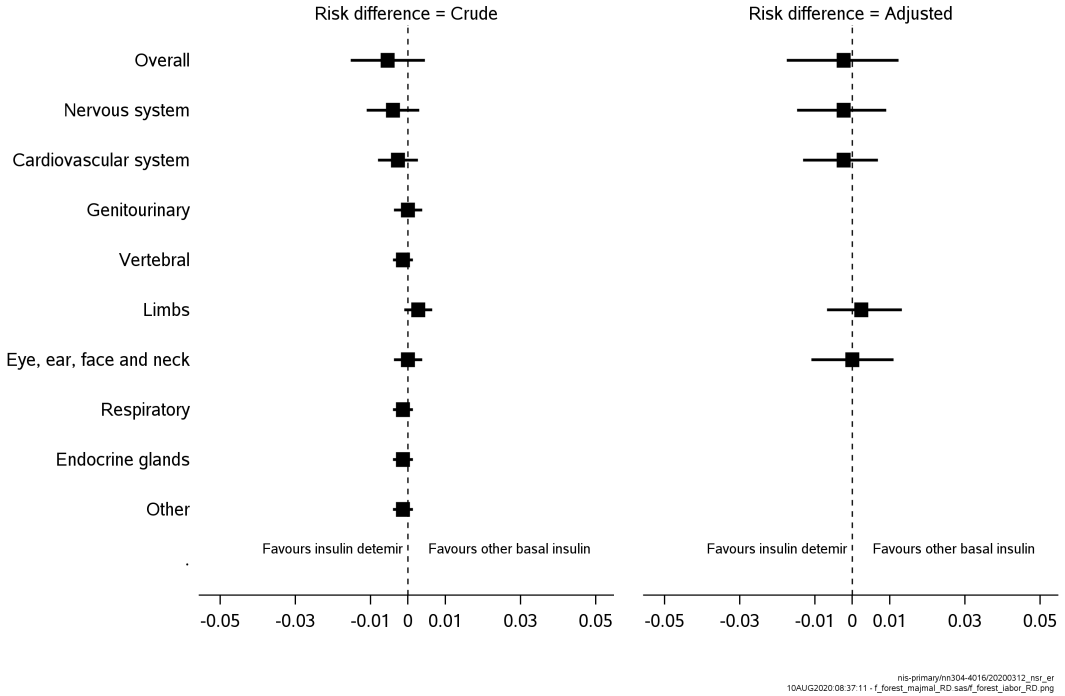
14.2.9 Risk difference of minor congenital malformation among liveborn infants born to mothers treated with basal insulin detemir compared to other basal insulins overall and by organ -forest plot – LIVEBORN



14.2.10 Odds ratio of induced abortion due to major malformations among foetus of mothers treated with basal insulin detemir compared to other basal insulins – forest plot – FOETUS analysis set



14.2.11 Risk difference of induced abortion among foetus of mothers treated with basal insulin detemir compared to other basal insulins – forest plot – FOETUS analysis set



14.3.3 Narratives of deaths, other serious and selected significant adverse events

Narrative cover page

This section contains narratives on: deaths; other serious adverse events; withdrawals due to adverse events; adverse events leading to permanent discontinuation of trial product; other significant non-serious adverse events; and pregnancies.

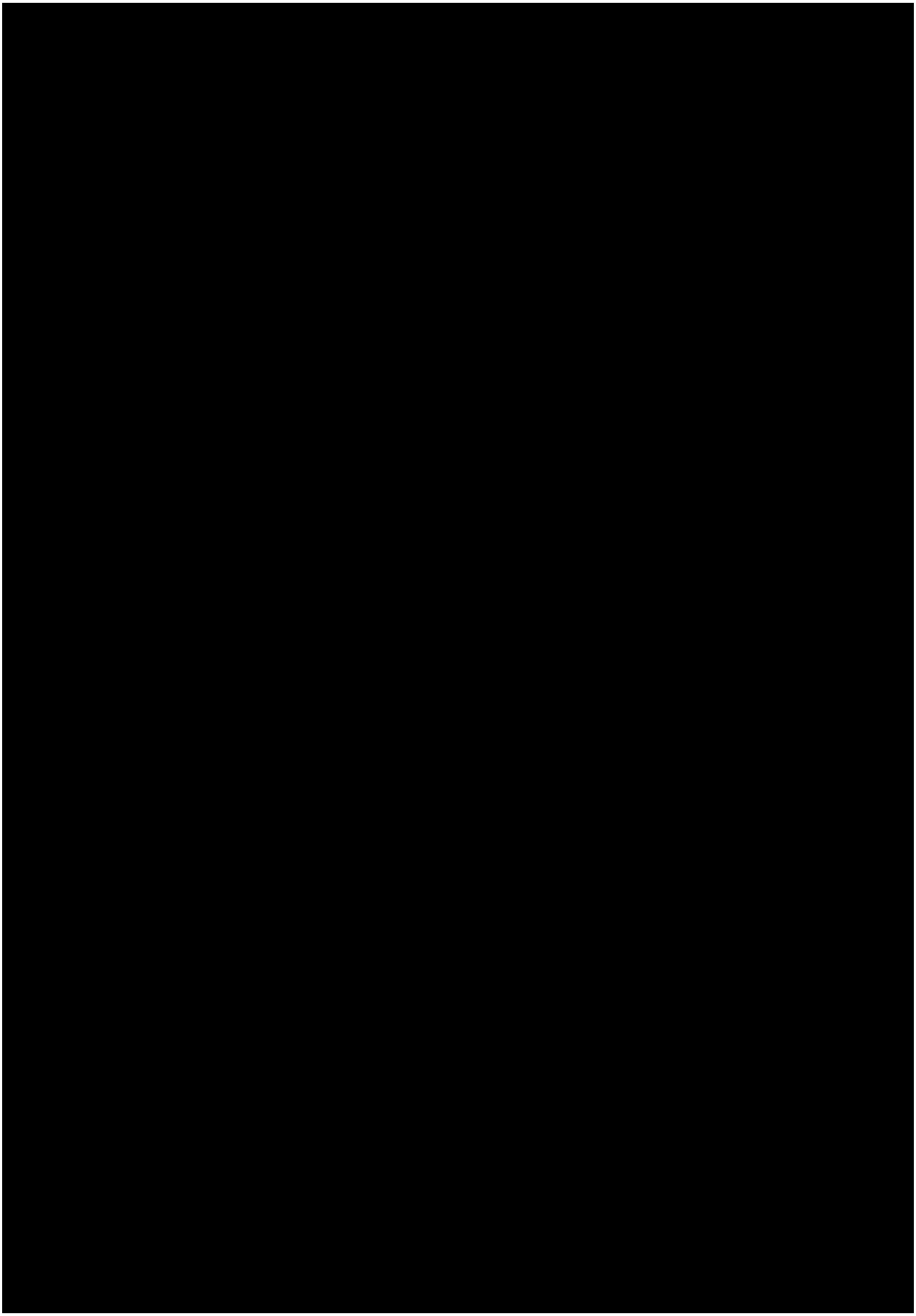
Narratives were extracted from the safety database (Global Safety, Novo Nordisk) on 23-December2019.

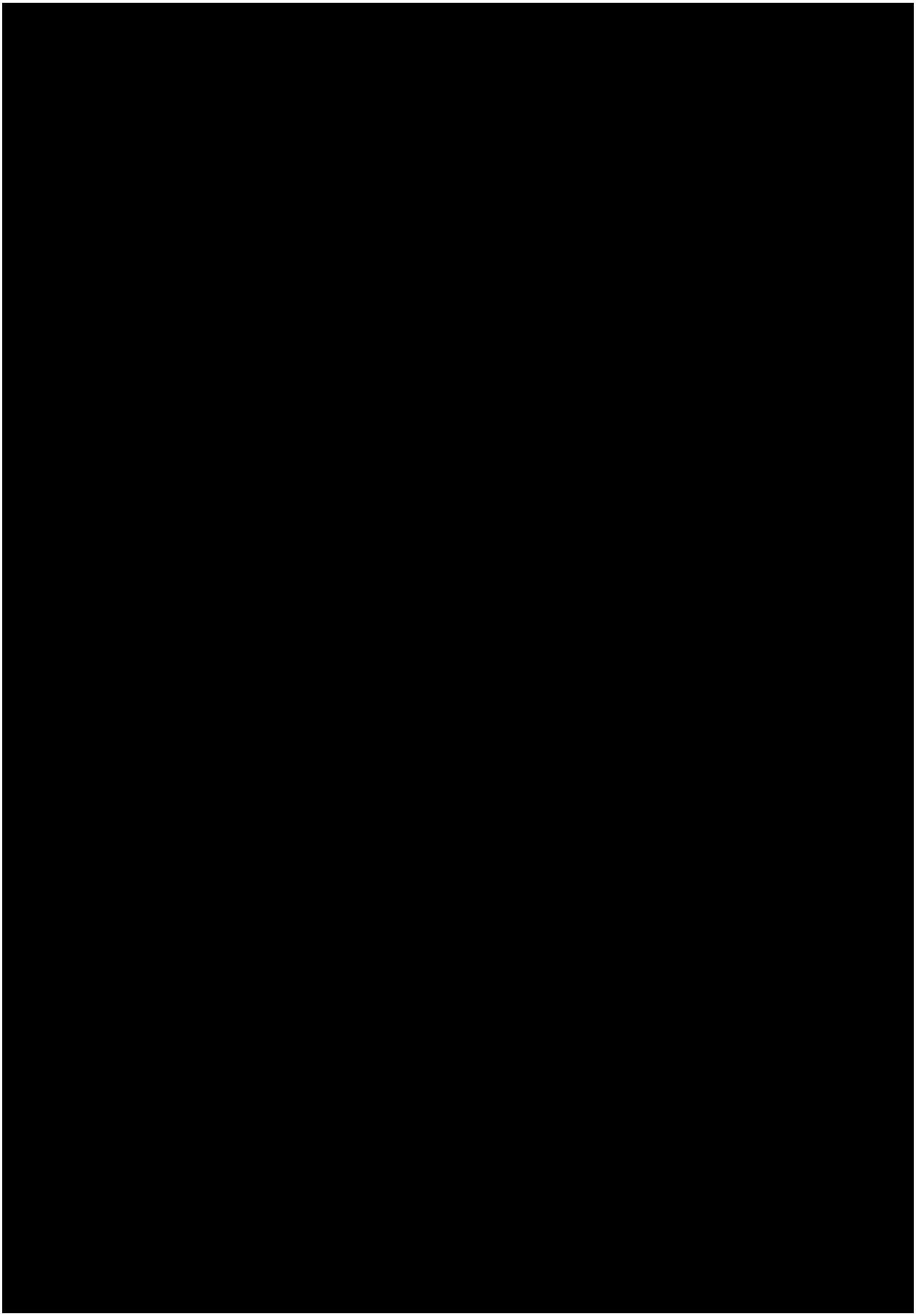
Narratives are bookmarked by category:

- deaths
- serious adverse events
- adverse events leading to withdrawal from trial
- pregnancies

If a case belongs to multiple categories, the case is bookmarked under all the categories to which it belongs

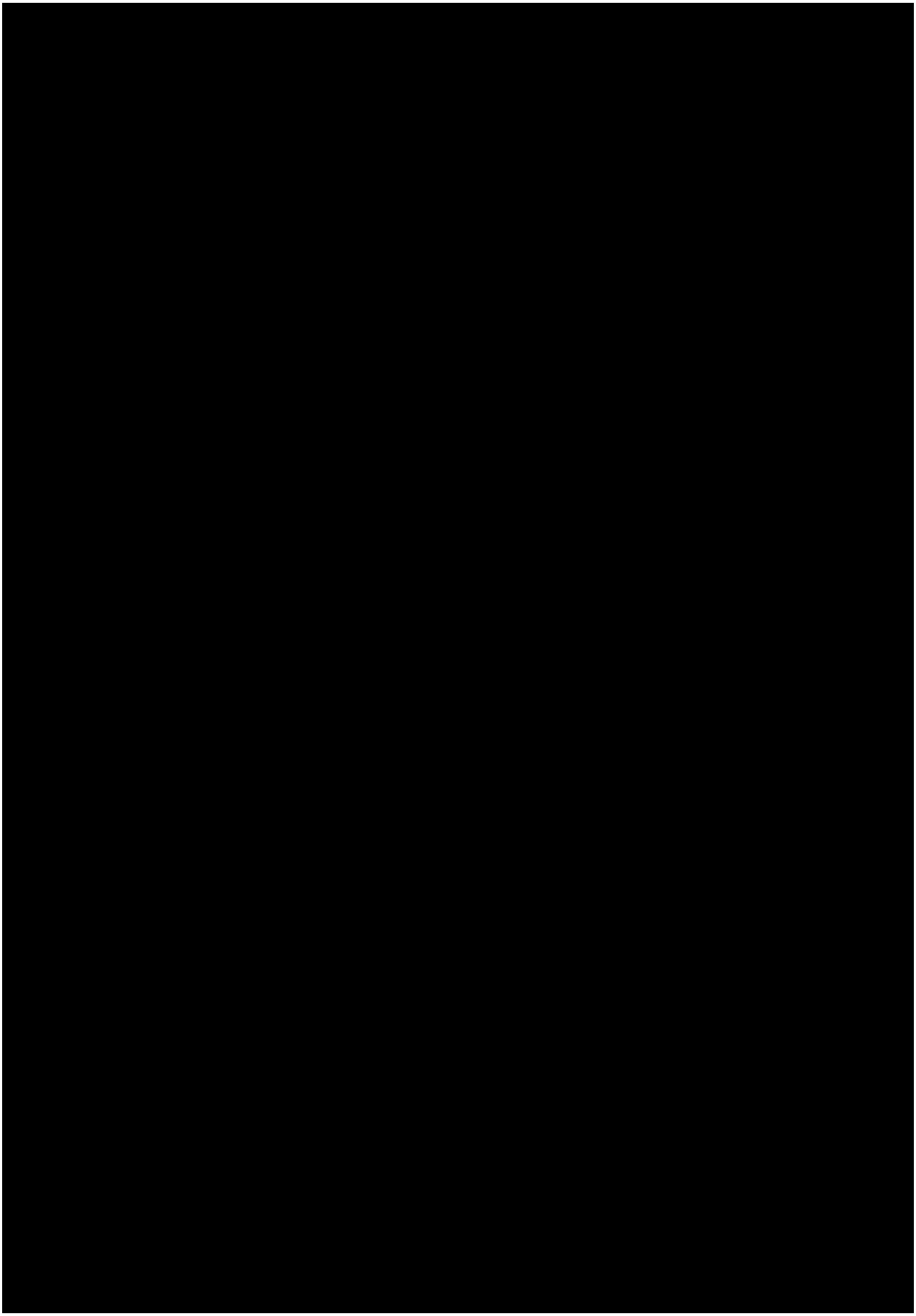
Subject ID	Case number	Reason(s) for narrative	Preferred term	Assigned treatment group
[redacted]				





[redacted]

[redacted]



[redacted]

[redacted]

[redacted]

[redacted]

Report #: **NN304-4016 Fatal Cases Narrative Line Listing** Date: 20-Dec-2019 07:45:04

Period: 01-Jan-1900 Through 20-Dec-2019

Ingredient: **Insulin Detemir**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
Study ID: NN304-4016 (**12**)								
Event System Organ Class: Cardiac disorders (**1**)								
[redacted]								

Report #: **NN304-4016 Fatal Cases Narrative Line Listing** Date: 20-Dec-2019 07:45:04

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
[redacted]								

Report #: **NN304-4016 Fatal Cases Narrative Line Listing** Date: 20-Dec-2019 07:45:04

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
[redacted]								

Report #: **NN304-4016 Fatal Cases Narrative Line Listing** Date: 20-Dec-2019 07:45:04

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
[redacted]								

Report #:

NN304-4016 Fatal Cases Narrative Line Listing

Date: 20-Dec-2019 07:45:04

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
[redacted]								

Report #:

NN304-4016 Fatal Cases Narrative Line Listing

Date: 20-Dec-2019 07:45:04

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
[redacted]								

Report #:

NN304-4016 Fatal Cases Narrative Line Listing

Date: 20-Dec-2019 07:45:04

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
[redacted]								

Report #:

NN304-4016 Fatal Cases Narrative Line Listing

Date: 20-Dec-2019 07:45:04

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
[redacted]								

Report #: **NN304-4016 Fatal Cases Narrative Line Listing** Date: 20-Dec-2019 07:45:04

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	[Preferred Term]	Patient Outcome
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[redacted]								

Report #: **NN304-4016 SAE Narrative Line Listing** Date: 23-Dec-2019 17:23:09

Period: 01-Jan-1900 Through 20-Dec-2019

Ingredient: **Insulin Detemir**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term]	Patient Outcome
Study ID: NN304-4016 ([redacted])								
[redacted]								

[3] Unlocked Case.

Report #: **NN304-4016 SAE Narrative Line Listing** Date: 23-Dec-2019 17:23:09

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term]	Patient Outcome
[redacted]								

[3] Unlocked Case.

Report #: **NN304-4016 SAE Narrative Line Listing** Date: 23-Dec-2019 17:23:09

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term]	Patient Outcome
[redacted]								

[3] Unlocked Case.

Report #: **NN304-4016 SAE Narrative Line Listing** Date: 23-Dec-2019 17:23:09

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term]	Patient Outcome
[redacted]								

[3] Unlocked Case.

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term]	Patient Outcome
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[3] Unlocked Case.

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[redacted]								

[3] Unlocked Case.

Report #: **NN304-4016 SUSAR Narrative Line Listing** Date: 20-Dec-2019 10:36:48

Period: 01-Jan-1900 Through 20-Dec-2019

Ingredient: **Insulin Detemir**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term]	Patient Outcome
Study ID: NN304-4016 ([redacted])								
[redacted]								

[3] Unlocked Case.

Report #: **NN304-4016 SUSAR Narrative Line Listing** Date: 20-Dec-2019 10:36:48

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term]	Patient Outcome
[redacted]								

[3] Unlocked Case.

Report #: **NN304-4016 SUSAR Narrative Line Listing** Date: 20-Dec-2019 10:36:48

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term]	Patient Outcome
[redacted]								

[3] Unlocked Case.

Report #: **NN304-4016 SUSAR Narrative Line Listing** Date: 20-Dec-2019 10:36:48

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term]	Patient Outcome
[redacted]								

[3] Unlocked Case.

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term]	Patient Outcome
[redacted]								

[3] Unlocked Case.

Report #: **NN304-4016 Blinded case Narrative Line Listing of un-blinded cases** Date: 23-Dec-2019 09:20:37

Period: 01-Jan-1900 Through 20-Dec-2019

Ingredient: **Insulin Detemir**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term]	Patient Outcome
Study ID: NN304-4016								
[redacted]								

[3] Unlocked Case.

Report #: **NN304-4016 Blinded case Narrative Line Listing of un-blinded cases** Date: 23-Dec-2019 09:20:37

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[redacted]								

[3] Unlocked Case.

Report #: **NN304-4016 Blinded case Narrative Line Listing of un-blinded cases** Date: 23-Dec-2019 09:20:37

Period: 01-Jan-1900 Through 20-Dec-2019

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term]	Patient Outcome
[redacted]								

[3] Unlocked Case.

Report #:

Request_id_61 MESI/AESI Narrative Line Listing

Date: 23-Dec-2019 09:39:24

Period: 01-Jan-1900 Through 20-Dec-2019

Ingredient: **Insulin Detemir**

Case Number	Country Source	Age Sex	Daily Dose [Dose Frequency]	Form / Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term]	Patient Outcome

No Data Found

Trial: NN304-4016

Clinical Trial Report Version 1.0 dated 17 Aug 2020

Overview of deleted pages

Page	Section	Title
372-661	14.3.3	Narrative cover pages
673-686	14.3.3	Fatal Cases Narrative Line Listing
697-4116	14.3.3	SAE Narrative Line Listing
4128-4282	14.3.3	SUSAR Narrative Line Listing
4294-8459	14.3.3	Blinded case Narrative Line Listing of un-blinded cases

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Appendices

Annex 1. List of stand-alone documents

Number	Document reference number	Date	Title
1	16.1.1	17 August 2020	Protocol and protocol amendments
2	16.1.2	17 August 2020	Sample case report form
3	16.1.3	17 August 2020	List of Independent Ethics Committees and/or Institutional Review Boards
4	16.1.4	17 August 2020	List and description of physicians in the study
5	16.1.5	17 August 2020	Signatures of principal or coordinating physicians and sponsor
6	16.1.6	17 August 2020	Audit certificates
7	16.1.7	17 August 2020	Documentation of statistical methods
8	16.1.9	17 August 2020	Publications based on the study
9	16.1.10	17 August 2020	Important publications referenced in the report

Annex 2. Additional information

Number	Document reference number	Date	Title
1	16.2.2	17 August 2020	Important protocol deviations
2	16.2.7	17 August 2020	Listings of adverse events (by subject) and/or technical complaints
3.	16.3.1	17 August 2020	Case report forms
4	16.3.2	17 August 2020	Other case report forms