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

First published: 05/07/2013
Last updated: 23/04/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/37403

EU PAS number
EUPAS4137

Study ID
37403

DARWIN EU® study
No

Study countries
Croatia
Denmark
Finland
France
Germany
Greece
Ireland
Israel
Italy
Malaysia

Netherlands
Norway
Poland
Portugal
Romania
Spain
United Kingdom

Study description
The purpose of the study (Diabetes Pregnancy Registry) is to evaluate the safety of treatment with insulin detemir in pregnant women with diabetes mellitus.

Study status
Finalised

Research institution and networks

Institutions

Novo Nordisk
First published: 01/02/2024
Last updated 01/02/2024
Institution

Multiple centres: 92 centres are involved in the study

Contact details

Study institution contact
Clinical Reporting Anchor and Disclosure (1452) Novo Nordisk
Study contact

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Primary lead investigator
Clinical Reporting Anchor and Disclosure (1452) Novo Nordisk
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
20/05/2013

Study start date
Actual:
30/09/2013

Date of final study report
Planned:
30/09/2020
Actual:
28/09/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

Study protocol

4016-protocol vers 2.0-redacted.pdf(461.68 KB)

4016-protocol-version-6-redacted.pdf(452.15 KB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:
Disease /health condition
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Safety study (incl. comparative)

Data collection methods:
Primary data collection

Main study objective:
The overall objective of the Diabetes Pregnancy Registry is to monitor and assess the safety of Levemir® use in pregnant women with diabetes mellitus (DM), and to monitor their infants at 1 month and 1 year of age.

Study Design

Non-interventional study design
Cohort
Other

Non-interventional study design, other
Post Authorisation Safety Study (PASS)

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name
INSULIN DETEMIR

Medical condition to be studied
Diabetes mellitus
Type 1 diabetes mellitus
Type 2 diabetes mellitus

Population studied

Short description of the study population
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.
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.
Exclusion criteria
1. Women who were pregnant for more than 16 weeks at baseline visit were excluded from the study.

Age groups
Adolescents (12 to < 18 years)
Adults (18 to < 46 years)
Adults (46 to < 65 years)

Special population of interest
Other
Pregnant women

Special population of interest, other
Diabetes mellitus patients

Estimated number of subjects
2446

Study design details

Outcomes
Comparison of the proportion of pregnancies in pregnant women who have completed 22 weeks of pregnancy and treated with Levemir® to pregnant women who have completed 22 weeks of pregnancy and treated with other basal insulin regimens resulting in none of

the following events:- Major congenital malformations- Perinatal death- Neonatal deathAssessed at up to 4 weeks after delivery. Incidence of major hypoglycaemiaProportion of pregnancies complicated by pre-eclampsiaProportion of pregnancies resulting in perinatal deathProportion of pregnancies resulting in neonatal deathProportion of pregnancies resulting in spontaneous abortionProportion of pregnancies resulting in pre-term deliveryHeight WeightProportion with changes of major congenital malformations

Data analysis plan
Continuous variables will be summarised with descriptive statistics and categorical variables will be displayed in frequency tables.

Documents

Study results
4016-nsr-nn-trials-redacted.pdf(3.54 MB)

Study report
4016-eu-regulatory-annual-report-20151101-20161031.pdf(144.5 KB)
4016-eu-regulatory-annual-report-20161101-20171031.pdf(145.17 KB)
4016-eu-regulatory-annual-report-20171101-20181031.pdf(175.83 KB)
4016-eu-regulatory-study-progress-report-20141101-20151031.pdf(145.61 KB)

Study, other information
4016-eu-regulatory-annual-report-20161101-20171031.pdf(145.17 KB)
4016-eu-regulatory-annual-report-20171101-20181031.pdf(175.83 KB)
4016-eu-regulatory-study-progress-report-20141101-20151031.pdf(145.61 KB)

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping
No

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
No