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

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 institutions 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 pactadmin@novonordisk.com

Study contact

pactadmin@novonordisk.com

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 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