

# 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
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### **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.

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### **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

Study contact

[pactadmin@novonordisk.com](mailto: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

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**Study start date**

Actual: 30/09/2013

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**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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**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

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**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

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### **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.

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#### **Age groups**

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

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#### **Special population of interest**

Other

Pregnant women

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#### **Special population of interest, other**

Diabetes mellitus patients

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#### **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

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### **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)

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### **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

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## **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

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## **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

No