

# NN304-4528: Retrospective Cohort study of all-Cause and Cardiovascular Mortality in type 2 diabetes patients using basal insulin Detemir and Glargine

**First published:** 14/05/2019

**Last updated:** 14/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS29708

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### Study ID

35510

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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### Study description

This study will examine the influence of the basal insulins Detemir and Glargine on risk of cardiovascular death and death from all causes in patients treated by their general practitioner in United Kingdom (UK).

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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

### Contact details

#### Study institution contact

Clinical Reporting Anchor and Disclosure (1452) Novo Nordisk A/S [pactadmin@novonordisk.com](mailto:pactadmin@novonordisk.com)

Study contact

[pactadmin@novonordisk.com](mailto:pactadmin@novonordisk.com)

#### Primary lead investigator

# Clinical Reporting Anchor and Disclosure (1452) Novo Nordisk A/S

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 18/03/2019

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### Study start date

Planned: 21/05/2019

Actual: 21/05/2019

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### Date of final study report

Planned: 20/05/2020

Actual: 18/05/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novo Nordisk A/S

## Study protocol

[4528-protocol-eu-pas-reg-redacted.pdf](#) (366.55 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

**Other study registration identification numbers and links**

UTN: U1111-1233-0930

**Methodological aspects**

**Study type**

**Study type list**

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The overall objective is to estimate the differences in all-cause and cardiovascular mortality rates between new users of basal insulin Glargine and Detemir in a population-based study of type 2 diabetes patients 40 years or older in UK in the years 2004-2018.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Post Authorisation Safety Study

## Study drug and medical condition

**Medical condition to be studied**

Type 2 diabetes mellitus

## Population studied

**Short description of the study population**

The study population comprised insulin-naïve patients with T2D, aged 40 years or above initiating therapy with basal insulins detemir or insulin glargine between 24 June 2004 and 10 May 2019.

T2D patients were defined as a record of a read code for T2D, without any record of a read code for type 1 diabetes (T1D) ever in the database. New users of insulin detemir or insulin glargine was defined as a record of a prescription of one of these treatments at or after 24 June 2004, as this was the date where both drugs occurred in the database, and thus were available for prescription in the UK. Only insulin-naïve patients without history of prescription of any type of insulin were included. Moreover, only patients with acceptable research quality data from one year prior to initiation of insulin detemir or insulin glargine were included in the study (i.e. only patients flagged as acceptable patients in the database were included and moreover the latest of the CPRD variables up to standard date (uts) and current registration date (crd) should be at least one year prior to initiation).

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### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Special population of interest**

Other

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

Type 2 diabetes mellitus patients

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### **Estimated number of subjects**

10000

## Study design details

### Outcomes

1. Age at all cause death or censoring
  2. Age at death of cardiovascular disease
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### Data analysis plan

Kaplan-Meier curves for survival will be estimated for the cohort, and Cox's proportional hazards (PH) models will be used to calculate adjusted hazard ratios (HRs) with 95% confidence intervals (CI) for mortality associated with insulin use. Age will be used as the underlying time-scale in the model. P-values of less than 0.05 will be considered statistically significant. The Cox's PH model will be adjusted for selected potential confounders as well as for the time dependent variables as described in section "P". The PH assumption for basal insulin and gender will be examined by plotting the stratified Kaplan-Meier curves and by residual plots. Continuous variables will be tested for linearity by including a squared term in the model.

## Documents

### Study results

[4528-nsr-report-encepp-redacted.pdf](#) (232.54 KB)

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## Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### **Data source(s)**

Clinical Practice Research Datalink

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### **Data source(s), other**

CPRD

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### **Data sources (types)**

[Disease registry](#)

[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