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

Study ID

35510

DARWIN EU® study

No

Study countries

☐ United Kingdom

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).

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

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Study contact

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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

Study start date
Planned: 21/05/2019

Actual: 21/05/2019

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

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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

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 2diabetes patients 40 years or older in UK in the years 2004-2018.

Study Design

Non-interventional study design

Cohort

Other

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).

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)

Special population of interest

Other

Special population of interest, other

Type 2 diabetes mellitus patients

Estimated number of subjects

10000

Study design details

Outcomes

1. Age at all cause death or censoring2. 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 betested for linearity by including a squared term in the model.

Documents

Study results

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

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Data source(s), other

CPRD

Data sources (types)

Disease registry

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