NN1250-4189 A multi-centre, prospective, non-interventional study of insulin degludec investigating the safety and effectiveness in a real world population with type 1 and 2 diabetes mellitus (ReFLeCT)

First published: 12/03/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7880

Study ID

29493

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Italy

- [ ] Netherlands
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

This study is conducted in Europe.The aim of the study is to investigate the safety and effectiveness of insulin degludec (Tresiba®) in a real world population with type 1 (T1DM) and 2 (T2DM) 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: 200 centres are involved in the study

Contact details

Study institution contact

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

Study contact

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: 05/11/2014

Study start date

Planned: 16/03/2015

Actual: 16/03/2015

Date of final study report

Planned: 19/03/2019

Actual: 27/03/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

Study protocol

4189-protocol-version-2-redacted.pdf(463.25 KB)

4189-protocol-version-5-redacted.pdf(555.04 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective is to monitor and assess the safety of Tresiba®, used with any other anti diabetic treatment and according to label, by analysing whether treatment with Tresiba® OD is associated with a change in the rate of any hypoglycaemic episodes occurring during the observation period, compared to the rate of any hypoglycaemic episodes occurring during the baseline period.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

INSULIN DEGLUDEC

Medical condition to be studied

Diabetes mellitus

Type 1 diabetes mellitus

Type 2 diabetes mellitus

Population studied

Short description of the study population

Male or female patients aged ≥18 years of age with either T1DM or T2DM (insulin using) (clinically diagnosed) prior to visit 1, who signed an informed consent form, and whose physician plans to start Tresiba® treatment.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Diabetes mellitus patients

Estimated number of subjects

1262

Study design details

Outcomes

Change in the number of any hypoglycaemic episodes, Change from baseline in HbA1c (glycosylated haemoglobin)Change from baseline in FPG (Fasting Plasma Glucose)Change from the baseline period in the number of severe hypoglycaemic episodesChange from baseline in HR-QoL (health-related quality of life) questionnaire scores (PROs (patient reported outcome): SF-36 (short form 36), and DTSQ(Diabetes Treatment Satisfaction Questionnaire))

Data analysis plan

All observational endpoints will be analysed on the full analysis set (FAS). The FAS includes all patients who received at least 1 dose of Tresiba® at visit 2. Patients who complete visit 1 but do not initiate Tresiba® at visit 2 will be excluded from the analysis.Patients will be analysed separately based on being T1DM or T2DM patients treated with insulin.

Documents

Study results

4189-nsr-eu-pas-reg-redacted.pdf(1.15 MB)

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 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

Unknown