NN1250-4129 A multi-centre, prospective, open-label, single-arm, non-interventional, post marketing surveillance (PMS) study of Tresiba® (insulin degludec) to evaluate long term safety and efficacy in patients with diabetes mellitus in routine clinical practice in India

First published: 05/05/2014

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6318

Study ID

23459

DARWIN EU® study

No

Study countries

India

Study description

This study is conducted in Asia.The aim of the study is to evaluate long term safety and efficacy of Tresiba® (insulin degludec) in patients with diabetes mellitus in routine clinical practice in India.

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 pactadmin@novonordisk.com

Study contact

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Primary lead investigator

Clinical Reporting Anchor and Disclosure (1452) Novo Nordisk

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 17/12/2013

Study start date

Planned: 24/07/2015

Actual: 24/07/2015

Date of final study report

Planned: 05/04/2018

Actual: 04/04/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

Study protocol

4129-protocol-version-1.0-Redacted.pdf (492.81 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:

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To assess the safety of long-term treatment with insulin degludec (Tresiba®) in insulin requiring patients with diabetes mellitus, initiating treatment with Tresiba® under routine clinical practice in India.

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

Type 1 diabetes mellitus

Type 2 diabetes mellitus

Population studied

Short description of the study population

Patients with diabetes mellitus requiring insulin therapy who qualify for starting treatment with Tresiba® based on the clinical judgment by their treating physician during enrolment period.

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 1&2 diabetes mellitus patients

Estimated number of subjects

1.056

Study design details

Outcomes

Incidence of adverse events (AEs) by preferred term, - Incidence of serious adverse events (SAEs) by preferred term- Incidence of serious adverse drug reactions (SADRs) by preferred term- Incidence of adverse drug reactions (ADRs) by preferred term- Incidence of severe hypoglycaemia- Change from baseline in glycosylated haemoglobin (HbA1c)- Change from baseline in fasting plasma glucose (FPG)- Incidence of confirmed hypoglycaemia

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Data analysis plan

No formal statistical testing will be done in this non-interventional trial.All continuous and categorical endpoints will be analysed using descriptive statistics.

Documents

Study results

4129-nsr-redacted.pdf (2.17 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