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

PURI
https://redirect.ema.europa.eu/resource/23459

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 institution 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
Study contact

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Primary lead investigator
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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 and secondary data collection

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
1056

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

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

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