NN5401-4149 A multi-centre, open-label, single-arm, non-interventional, post marketing surveillance (PMS) study of insulin degludec /insulin aspart in patients with diabetes mellitus in routine clinical practice in India

First published: 29/08/2014

Last updated: 02/04/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/24261

EU PAS number
EUPAS6587

Study ID
24261

DARWIN EU® study
No

Study countries
India

Study description
This trial is conducted in Asia.The aim of this trial is to evaluate long term safety and efficacy in patients with diabetes mellitus in routine clinical practice in India.

Study status
Finalised

Research institution and networks

Institutions

Novo Nordisk

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Institution

Contact details

Study institution contact
Clinical Reporting Anchor and Disclosure (1452) Novo Nordisk

Study contact

pactadmin@novonordisk.com
Primary lead investigator
Clinical Reporting Anchor and Disclosure (1452) Novo Nordisk

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
17/06/2014

Study start date
Planned:
01/12/2015
Actual:
24/11/2015

Date of final study report
Planned:
01/06/2018
Actual:
31/05/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

Study protocol

4149-protocol-version-1.0-Redacted.pdf(317.23 KB)

Regulatory

Was the study required by a regulatory body?
Yes

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/ insulin aspart (Ryzodeg™) in insulin requiring patients with diabetes mellitus, initiating treatment with Ryzodeg™ 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
INSULIN ASPART

Medical condition to be studied
Diabetes mellitus
Type 1 diabetes mellitus
Type 2 diabetes mellitus

Population studied

Short description of the study population
Patients with insulin requiring diabetes mellitus and who were scheduled to start treatment with Ryzodeg™ based on the clinical judgment of their treating physician.

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
1029

Study design details

Outcomes
Incidence of Adverse Events (AEs), Serious Adverse Events (SAEs)Serious Adverse Drug Reactions (SADRs) Adverse Drug Reactions (ADRs) Severe or Blood glucose(BG) Confirmed hypoglycaemia Change in HbA1c (glycosylated haemoglobin)Change in Fasting Plasma Glucose (FPG)Change in Post Prandial Blood/Plasma Glucose (PPBG/PPPGThe reason for initiating or intensifying treatment with Ryzodeg™

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
4149-nsr-redacted.pdf(1.79 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