NN5401-4149 A multi-centre, open-label, single-arm, non-interventional, post marketing sur-veillance (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





## Administrative details

**EU PAS number** 

EUPAS6587

Study ID

24261

**DARWIN EU® study** 

No

**Study countries** 

	India
1	IIIaia

#### **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 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

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 bo	dy?
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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 data collection and secondary use of data

#### Main study objective:

To assess the safety of long-term treatment with insulin degludec/ insulin aspart (Ryzodeg<sup>™</sup>) in insulin requiring patients with diabetes mellitus, initiating

treatment with Ryzodeg<sup>™</sup> 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 $^{\text{m}}$  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**

# 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

# Unknown Check completeness Unknown

## **Check stability**

**Check conformance** 

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

Unknown