NN7088-4557: Adverse Event Data Collection from the EUHASS Registry on Turoctocog alfa pegol

First published: 05/01/2021

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS33777

Study ID

50382

DARWIN EU® study

No

Study countries

- ☐ Afghanistan
- ☐ Albania

Study description

This non-interventional study concerns a safety data collection based on adverse event data from a third-party registry (European Haemophilia Safety Surveillance System, EUHASS) that includes information about adverse events from patients with haemophilia A treated with turoctocog alfapegol. There is no extra burden to the patients by participating in this registry-based data collection.

Study status

Ongoing

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 & Disclosure (1452) Novo Nordisk A/S PACTADMIN@novonordisk.com

Study contact

PACTADMIN@novonordisk.com

Primary lead investigator

Clinical Reporting Anchor & Disclosure (1452) Novo Nordisk A/S

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 17/12/2019

Study start date

Planned: 09/12/2020

Actual: 09/12/2020

Date of final study report

Planned: 10/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

Study protocol

_ Protocol 4557 protocol eu-pas-reg redacted.pdf (275.77 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

U1111-1235-5939

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To investigate the safety of long-term exposure to turoctocog alfa pegol in patients with haemophilia A.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

TUROCTOCOG ALFA PEGOL

Medical condition to be studied

Haemophilia A without inhibitors

Population studied

Age groups

- Adolescents (12 to < 18 years)
- 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)

Estimated number of subjects

50

Study design details

Outcomes

Adverse events (AEs) reported to the registry with suspected relation to turoctocog alfa pegol, Adverse Drug Reactions (ADRs), in patients with haemophilia A for renal, hepatic and neurological events. Other AEs reported to the registry during the study period with suspected relation to turoctocog alfa pegol in patients with haemophilia A including ADRs of special interest (de novo FVIII inhibitors equal to or above 0.6 Bethesda Units (BU)), anaphylaxis and other allergic reactions, thromboembolic events).

Data analysis plan

This is a purely descriptive study and the statistical analyses and presentations do not include any testing of pre-specified hypotheses.

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 source(s), other

EUHASS - Blood disorders

Data sources (types)

Disease registry

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

No