NN7999-4413: Adverse Event Data Collection from External Registries on Nonacog Beta Pegol

First published: 28/09/2018

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/27138

EU PAS number

EUPAS25696

Study ID

27138

DARWIN EU® study

No

Study countries

☐ Netherlands

United Kingdom

Study description

The purpose of this study is to collect data on adverse events from third party registries that include information about adverse events from patients with haemophilia B treated with nonacog beta pegol. The third party registries include PedNet Haemophilia Registry (PedNet) and the European Haemophilia Safety Surveillance System (EUHASS). Data from national and international registries in countries where nonacog beta pegol has been approved and marketed could be included in the data collection.

Study status

Ongoing

Research institutions and networks

Institutions

Novo Nordisk

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Institution

Contact details

Study institution contact

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

Study contact

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Primary lead investigator

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

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/08/2017

Actual: 14/09/2018

Study start date

Planned: 01/10/2018

Actual: 01/10/2018

Date of final study report

Planned: 01/10/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

Study protocol

4413-protocol-eu-pas-reg-redacted.pdf(225.45 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

UTN:U1111-1212-4050NCT:NCT03690336

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:

The purpose of this study is to collect data on adverse events from third party registries that include information about adverse events from patients with haemophilia B treated with nonacog beta pegol.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

REFIXIA

Medical condition to be studied

Haemophilia B with anti factor IX

Haemophilia B without inhibitors

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

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

10

Study design details

Outcomes

Adverse Drug Reactions (ADRs) reported to the registries with suspected relation to nonacog beta pegol in patients with haemophilia B, Other ADRs reported to the registries during the study period with suspected relation to nonacog beta pegol in patients with haemophilia B

Data analysis plan

This is a purely descriptive study and the statistical analyses and presentations do not include any testing of pre-specified hypothesesNovo Nordisk will be responsible for all statistical analyses.

Data management

Data sources

Data source(s)

PedNet Haemophilia registry

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