NN1841-3868 Use of rFXIII in treatment of congenital FXIII deficiency, a prospective multi-centre observational study (mentor™6)

First published: 27/05/2013

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS3687

Study ID

36010

DARWIN EU® study

No

Study countries

Canada

Denmark

Hungary

Italy

Spain

United Kingdom

United States

Study description

This study is conducted globally.The aim of this observational study is to investigate the incidence of specific adverse drug reactions associated with the use of recombinant factor XIII (NovoThirteen®) in patients with congenital FXIII A-subunit deficiency (congenital FXIII deficiency), comprising FXIII antibodies, allergic reactions, embolic and thrombotic events and lack of therapeutic effect.The study will aim at observing all patients exposed to NovoThirteen® in the EU, and additional patients from selected non-EU countries. Recombinant FXIII (rFXIII) is registered in EU and Switzerland as NovoThirteen® and in Canada as Tretten®.

Study status

Finalised

Research institutions and networks

Institutions

Novo Nordisk

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 17 centres are involved in the study

Contact details

Study institution contact

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Study contact

pactadmin@novonordisk.com

Primary lead investigator

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

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/05/2013

Study start date

Actual: 17/05/2013

Date of interim report, if expected

Planned: 30/10/2015

Actual: 09/11/2015

Date of final study report
Planned: 29/06/2020

Actual: 25/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

Study protocol

3868-updated-protocol-no-3-version-1-redacted.pdf (415.59 KB)

3868-updated-protocol-no-4-version-2-redacted.pdf (418.86 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)

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:

Primary data collection

Main study objective:

The aim of this observational study is to investigate the incidence of specific adverse drug reactions associated with the use of recombinant factor XIII (rFXIII) in patients with congenital FXIII A-subunit deficiency, comprising FXIII antibodies, allergic reactions, embolic and thrombotic events and lack of therapeutic effect.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, single-arm, multi-centre post-authorisation safety study (PASS)

Study drug and medical condition

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

CATRIDECACOG

Medical condition to be studied

Factor XIII deficiency

Population studied

Short description of the study population

This non-interventional study will include patients with congenital FXIII A-subunit deficiency for whom the decision to treat with rFXIII has been made and who are willing to provide informed consent (or patient’s legally acceptable representative (LAR) consent, if applicable). The study will aim at observing all patients exposed to rFXIII in the EU, and additional patients from selected nonEU countries. The study will run for 5 years, where after data will be reported and the study closed.

Inclusion criteria

1. Informed consent obtained before any study-related activities. (Study-related activities are any procedure related to recording of data according to the protocol).
2. Able and willing to provide signed informed consent (or patient’s legally acceptable representative (LAR) consent, if applicable), as required by local ethics committee, governmental or regulatory authorities.
3. Congenital FXIII A-subunit deficiency.
4. Actual or planned exposure to the rFXIII.

Exclusion criteria

1. Mental incapacity, unwillingness or language barriers precluding adequate understanding or cooperation.

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Preterm newborn infants (0 – 27 days)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Special population of interest

Other

Special population of interest, other

Congenital FXIII deficiency patients

Estimated number of subjects

30

Study design details

Outcomes

Adverse drug reactions in patients with congenital FXIII A-subunit deficiency treated with rFXIII, comprising FXIII antibodies, allergic reactions, embolic and thrombotic events and lack of effect, collected during study period up to 6 years. - All serious adverse events collected- All medical events of special interest collected- All medication errors and near medication errors collected- Use of rFXIII in patients with congenital FXIII A-subunit deficiency also for other uses than for prophylactic treatment collected- Annualised bleeding rate- All outcomes are collected during study period up to 6 years

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Data analysis plan

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

Documents

Study results

3868-nsr-report-encepp-redacted.pdf (1.95 MB)

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

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No