TAK-577-4005: Estimating Risk of Selected Adverse Events in Patients with Von Willebrand Disease Treated With VEYVONDI® (Vonicog Alfa; Recombinant Von Willebrand Factor)

First published: 03/03/2022

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS45617

Study ID

48320

DARWIN EU® study

No

Study countries

Austria

Denmark

France
Germany
Netherlands
Norway
Sweden
United Kingdom (Northern Ireland)

Study description

The main aim of this study is to estimate the risks of certain adverse events in adults with Von Willebrand Disease treated with VEYVONDI. No study medicines will be provided to participants in this study. Data from medical records of participants diagnosed with Von Willebrand Disease and treated with VEYVONDI will be evaluated during this study.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Takeda Study contact TrialDisclosures@takeda.com

Study contact

TrialDisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/09/2021

Actual: 23/09/2021

Study start date

Planned: 01/05/2022

Actual: 08/06/2022

Date of final study report

Planned: 30/12/2022

Actual: 04/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

tak-577-4005-protocol-original_redact.pdf (1.24 MB)

TAK-577-4005-clinical-study-protocol-redact.pdf (1.48 MB)

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

ClinicalTrials.gov Identifier: NCT05265078

https://clinicaltrials.gov/ct2/show/NCT05265078,,https://clinicaltrials.takeda...

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 estimate risk of hypersensitivity reactions, thromboembolic events, and VWF or FVIII inhibitor formation after treatment with VEYVONDI in study population for treatment of haemorrhage, surgical bleeding and prevention of surgical bleeding when DDAVP treatment alone is ineffective or not indicated and describe association of thromboembolic events with use of FVIII.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Von Willebrand's disease

Population studied

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)

Estimated number of subjects

80

Study design details

Outcomes

The primary outcomes will assess the percentage of participants who experienced hypersensitivity reactions, thromboembolic events, and with VWF or factor VIII (FVIII) inhibitor formation.

Data analysis plan

Descriptive statistics will be generated within each data source to describe study population. Categorical variables will be summarized by frequencies and proportions, and continuous variables will be summarized as the mean with standard deviation (SD) or standard error (SE) and range for normally-distributed variables, median, interquartile range (IQR) and range for non-normally-distributed variables.

Documents

Study report

TAK-577-4005-clinical-study-report-redact.pdf (914.97 KB)

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

The primary source for this retrospective study is the electronic or paper medical records of enrolled participants. Participant’s data will be collected from the records and will be entered in a web-based electronic case report form (eCRF).

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