

A Prospective, Multicentre, Non-Interventional Study Evaluating the Bleeding Incidence in Patients with Von Willebrand Disease Undergoing On-Demand Treatment (WIL-29)

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Study

Finalised

Administrative details

EU PAS number

EUPAS29946

Study ID

42926

DARWIN EU® study

No

Study countries

Belarus

Bulgaria

- Hungary
 - Moldova, Republic of
 - Russian Federation
 - Ukraine
 - United States
-

Study description

The primary objective of this study is to characterise the bleeding and treatment pattern of patients with type 3, type 2 (except 2N), or severe type 1 von Willebrand disease receiving routine on-demand treatment with a von Willebrand factor-containing product.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

Cristina Solomon cristina.solomon@octapharma.com

Study contact

cristina.solomon@octapharma.com

Primary lead investigator

Sidonio Jr.. Robert

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/02/2019

Actual: 18/02/2019

Study start date

Planned: 18/07/2019

Actual: 18/07/2019

Data analysis start date

Planned: 30/06/2020

Date of final study report

Planned: 01/12/2021

Actual: 27/08/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

If 'other', further details on the scope of the study

Characterization of bleeding events and treatment pattern

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to characterise the bleeding and treatment pattern of patients with type 3, type 2 (except 2N), or severe type 1 VWD undergoing routine ondemand treatment with a VWF-containing product.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This is a prospective, multicentre, international, non-controlled non-interventional study (NIS).

Study drug and medical condition

Medical condition to be studied

Von Willebrand's disease

Population studied

Short description of the study population

Patients with type 3, type 2 (except 2N), or severe type 1 VWD undergoing routine ondemand treatment with a VWF-containing product.

Age groups

- 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)
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Estimated number of subjects

56

Study design details

Outcomes

total annualised bleeding rate (TABR), Spontaneous annualised bleeding rate (SABR), VWF-containing product consumption, proportion of successfully treated bleeding Events. proportion of successfully treated surgeries, QoL, Safety

Data analysis plan

descriptive statistical methods.

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