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

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Study contact

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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

Octapharma AG

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)

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 succesfully treated bleeding Events. proportion of succesfully treated surgeries, QoL, Safety

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Data analysis plan

descriptive statistical methods.

Data management

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