

Surveillance of Efficacy and Tolerability in Von Willebrand's disease

Submission date 18/11/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 19/11/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 07/04/2011	Condition category Haematological Disorders	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
WIL-15

Study information

Scientific Title

Acronym
Wilate-SET

Study objectives

The efficacy of Wilate® in clinical practice is comparable to the efficacy in clinical trial patients.

As of 07/05/2011 the anticipated end date for this trial has been extended from 31/07/2009 to 31/07/2012

Ethics approval required

Old ethics approval format

Ethics approval(s)

As the procedures during this observational study do not interfere with the patient's usual treatment and monitoring of treatment, this study is not regarded as a clinical study as defined by EU Directive 2001/20/EC. Therefore approval by an Independent Ethical Committee as an Institutional Review Board is not required.

Study design

Non-interventional, observational, open, prospective, multi-centre study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Von Willebrand's disease

Interventions

Documentation of details of diagnosis and bleeding frequency at entry, details of bleeding episodes and surgical procedures during 2-year individual observation period. Documentation of details of each injection including assessment of efficacy and tolerability at a 4-point verbal rating scale. Documentation of relevant laboratory assessments if performed.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Wilate®

Primary outcome(s)

Percentage of efficacy assessments with rating "excellent/good".

Key secondary outcome(s)

Percentage of tolerability assessments with rating "excellent/good".

Completion date

31/07/2012

Eligibility

Key inclusion criteria

Patients (any age and gender) suffering from hereditary or acquired Von Willebrand's disease requiring von Willebrand factor (VWF)/coagulation factor eight (FVIII) concentrate.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

Does not comply with the above inclusion criteria

Date of first enrolment

01/02/2005

Date of final enrolment

31/07/2012

Locations

Countries of recruitment

Germany

Study participating centre

Octapharma GmbH

Langenfeld

Germany

40764

Sponsor information

Organisation

Octapharma GmbH (Germany)

ROR

<https://ror.org/002k5fe57>

Funder(s)

Funder type

Industry

Funder Name

Octapharma GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration