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Surveillance of Efficacy and Tolerability in Von Willebrand's disease

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Multi-centre

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
Percentage of tolerability assessments with rating "excellent/good".

Overall study start date
01/02/2005

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

Age group
Other

Sex
Both

Target number of participants
At least 30 patients

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)

Sponsor details
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Sponsor type
Industry

ROR
https://ror.org/002k5fe57

Funder(s)

Funder type
Industry

Funder Name
Octapharma GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration