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Surveillance of Tolerability And Treatment Efficacy of Wilate® in von Willebrands disease

Submission date
13/09/2012

Registration date
05/12/2012

Last Edited
09/05/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients with von Willebrand disease (a bleeding disorder that affects your blood's ability to clot) may require substitution with a coagulation factor concentrate like Wilate. In this study, data about the treatment with Wilate will be collected for safety surveillance and efficacy evaluations.

Who can participate?
All patients with von Willebrands disease in need for replacement therapy whos doctor had first decided to use Wilate and then to participate in the study can be included.

What does the study involve?
The treatment with Wilate will be the same as prescribed by the doctor without the study no additional interventions are required. Careful documentation of therapy by the doctor or in case of home treatment by the patient is necessary.

What are the possible benefits and risks of participating?
All information collected in the course of the treatment with Wilate will add knowledge on the use of Wilate and treatment of the von Willebrand disease under routine conditions. There are no risks arising from participation.

Where is the study run from?
The study will take place in several haemophilia centres in Germany.

When is the study starting and how long is it expected to run for?
June 2012 to May 2020

Who is funding the study?
Octapharma GmbH (Germany)

Who is the main contact?
Dr Susanne Seeger
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WIL-25

Study information

Scientific Title
Surveillance of Tolerability And Treatment Efficacy of Wilate® in von Willebrands disease: an observational study

Acronym
Wilate-STATE

Study objectives
Wilate 500/1000 is safe and efficacious for treatment of von Willebrand's disease in clinical practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Medical Faculty of Johann Wolfgang Goethe University Frankfurt/Main Germany, November 2012

Study design
Observational open prospective multi-centre study

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
von Willebrand's disease

Interventions
For this non-interventional study, details of the patient history and the current treatment with Wilate will carefully be recorded. This included information on of injections, duration and intensity of bleeding episodes and information regarding possible surgical interventions. The efficacy will be assessed according to a 4-point verbal rating scale. Suspected adverse drug reactions (side effects) will be documented. The observation time depends on the clinical needs of the patient, e.g. from a few days in case Wilate is required only to cover a surgery or until study end in case of prophylactic treatment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Wilate®

Primary outcome measure
Rate of adverse drug reactions. Laboratory parameters relevant to safety when documented

Secondary outcome measures
1. Percentage of efficacy rating "excellent" or "good" in bleeding episodes and surgeries
2. Bleeding frequency in prophylactically treated patients and - if available - course of laboratory parameters indicating anemia. Comparison of efficacy results with precursor study with Wilate 450/900 when feasible

Overall study start date
28/06/2012

Completion date

31/05/2020

Eligibility

Key inclusion criteria
1. The patient suffers from hereditary or acquired von Willebrand's disease and is in need for replacement of coagulation concentrate containing von Willebrand factor (VWF)
2. When bleeding history is positive, other causes were excluded

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

Key exclusion criteria
1. The patient could actually be treated with DDAVP (Desmopressin Acetate)
2. The patient has a von Willebrand factor activity over 70 % and there are no findings manifesting the von Willebrand (VWD) diagnosis like
2.1. Bleeding pattern compliant with VWD
2.2. Positive family history
2.3. Mutation analysis
2.4. Multimer pattern

Date of first enrolment
28/07/2012

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
Germany

Study participating centre
Elisabeth-Selbert-Str. 11
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Sponsor information

Organisation
Octapharma GmbH (Germany)

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Sponsor type
Industry

Website
http://www.octapharma-biopharmaceuticals.com

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