

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

Submission date 13/09/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/12/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/05/2017	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

Dr Susanne Seeger

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Langenfeld

Germany

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Sponsor information

Organisation

Octapharma GmbH (Germany)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes