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Pharmacokinetics of Wilate® and Haemate® P in von Willebrand type 3 patients: a prospective, randomised, controlled, open-labelled, two-arm cross-over study

Submission date
01/09/2008

Recruitment status
No longer recruiting

Registration date
04/09/2008

Overall study status
Completed

Last Edited
20/05/2019

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-001910-25

Protocol serial number
WIL-21

Study information

Scientific Title
Pharmacokinetics of Wilate® and Haemate® P in von Willebrand type 3 patients: a prospective, randomised, controlled, open-labelled, two-arm cross-over study

Study objectives
Comparison of pharmacokinetics of Wilate® and Haemate® P in von Willebrand type 3 patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Ethics Committee of SHAT "Joan Pavel" OOD hospital, Sofia on the 15th July 2008
2. Ethics Committee of FNsP Cyril and Method Hospital, Bratislava on the 24th June 2008

Primary study design
Interventional

Study design
Prospective, randomised, controlled, open-labelled, two-arm cross-over, multi-centre phase II study

Study type(s)
Treatment

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

Interventions
1. Wilate® vials of approximately 400 IU VWF:RCo
2. Haemate® P vials of approximately 500 VWF:RCo

One vial of freeze-dried concentrate is reconstituted in 0.1% polysorbate 80 solution/water for injection. A dose of at least 40 IU VWF:RCo/kg body weight will be given intravenously by bolus administration. Each product is administered once. Blood samples will be taken at the following time-points after each infusion: 30 minutes before and at 15 minutes, 30 minutes, 45 minutes, 1, 3, 6, 12, 24, 30, 48, and 72 hours after the infusion.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Wilate®, Haemate® P

Primary outcome(s)

The in-vivo half life (t1/2) of Wilate® is the primary endpoint and will be calculated for VWF ristocetin cofactor activity (VWF:RCo), FVIII:C, VWF antigen (VWF:Ag), and VWf collagen binding assay (VWF:CB).

Outcomes will be determined from plasma levels measured from samples taken at the above mentioned time-points.

Key secondary outcome(s)
1. Pharmacokinetics: the following parameters are secondary endpoints and will be calculated for VWF:RCo, FVIII:C, VWF:Ag and VWF:CB:
1.1. Area under the curve (AUC)
1.2. Maximum plasma concentration (Cmax)
1.3. Time to reach maximum plasma concentration (Tmax)
1.4. Mean residence time (MRT)
1.5. Volume of distribution (Vd)
1.6. Clearance (Cl)
For the calculation of these parameters, the labelled potency of the respective drug will be the taken. Outcomes will be determined from plasma levels measured from samples taken at the above mentioned time-points.
2. Recovery: in vivo incremental recovery of VWF:RCo, FVIII:C, VWF:Ag and VWF:CB will be calculated from the levels before and after the injection. For the calculation of recovery, the labelled potency of the respective drug will be the taken.
3. Tolerability: tolerability will be assessed by monitoring vital signs, haematological parameters (red blood cell [RBC] count, white blood cell [WBC] count, haemoglobin, haematocrit [HCT], and platelet count [PC]), and by monitoring adverse events (AEs)

Completion date
01/11/2008

Eligibility

Key inclusion criteria
1. Defined inherited von Willebrand disease (VWD) type 3
2. Male or female subject of at least 12 years of age and have a body weight of at least 32 kg but not more than 125 kg
3. Negative for hepatitis B surface antigen (HBsAg)
4. For human immunodeficiency virus (HIV)-positive subjects: must have a baseline CD4+ cell count of greater than 200/mm^3, and a platelet count of greater than 100,000/dL
5. Freely given written informed consent. For subjects who are not legally permitted to provide written consent, the consent must be provided by parents or legal guardians.
6. Females must promise to avoid becoming pregnant for visits 1 to 11

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Total final enrolment
9

Key exclusion criteria
1. Subjects with any other bleeding disorders
2. Known history of intolerance to plasma derivatives or blood products
3. Present or past inhibitor activity directed against any von Willebrand factor (VWF) /coagulation factor eight (FVIII) component
4. Severe liver or kidney disease
5. Participation in another clinical study involving an investigational treatment, either currently or within the 4 weeks prior to study entry. Studies consisting of data and blood sampling collections on a regular or long-term basis are exempt from this exclusion.
6. Subjects with excessive alcohol or illicit drug usage
7. Subjects who cannot comply with protocol requirements
8. Pregnant or lactating women

Date of first enrolment
01/09/2008

Date of final enrolment
01/11/2008

Locations

Countries of recruitment
Austria

Bulgaria

Slovakia

Study participating centre
Oberlaaerstrasse 235
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Sponsor information

Organisation
Octapharma AG (Switzerland)

ROR
https://ror.org/002k5fe57

Funder(s)

Funder type
Industry

Funder Name
Octapharma AG (Switzerland)

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?
Basic results			20/05/2019	No	No