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An open label phase I study in healthy subjects with blood group AB to investigate the safety, tolerability and efficacy of Uniplas™ LG

Submission date 22/12/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 10/01/2011	**Overall study status** Completed	
Last Edited 21/06/2011	**Condition category** Signs and Symptoms	

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
UNI-111

Study information

Scientific Title

Study objectives
This is a trial in healthy subjects who have blood group AB to investigate the safety, tolerability and efficacy of Uniplas™ LG.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee (Ethikkommission der med.Uni.Wien und des Allg. Krankenhauses der Stadt Wien AKH) approved on the 12th November 2010 (ref: 779/2010)

Study design
Open-label non-randomised non-controlled phase I study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Substitution of intentionally removed plasma

Interventions
Primary objective of this study is to investigate the safety and the tolerability of Uniplas™ LG, assessed by clinical and laboratory parameters with respect to subjects with blood group AB. IMP will be infused once and the subjects will be followed up until 3 months after administration of the IMP.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Uniplas™ LG

Primary outcome(s)
Haemoglobin (Hb), measured at baseline, less than or equal to 30 minutes before and less than 5 minutes post plasmapheresis, 15 minutes and 2 hours post-transfusion, 24 hours and 7 days post-plasmapherese and 3 months after administration of IMP.

Key secondary outcome(s))
1. Parameters of haemolysis: haptoglobin, free Hb, indirect bilirubin
2. Complement activation: CH50, C3c, C4
3. Circulating immune complexes (CIC): IgG, IgA, IgM
4. DAT (direct antiglobulin test)
5. Isoagglutinines (in case of a positive DAT)
6. Haematology: RBC count, WBC count, platelets, Hct, Hb

7. Standard safety lab (Clinical chemistry): sodium (Na+), potassium (K+), calcium (Ca2+), creatinine, ALAT, gamma-glutamyl transferase (gGT), total protein (TP)
8. Haemostatic Panel I: aPTT, PT, Fbg
9. Haemostatic Panel II: FII, FV, FVII, FVIII, FIX, FX, FXI, Protein C, Protein S, plasmin inhibitor)
10. Urine analysis: WBC, nitrite, pH, protein, glucose, ketones, urobilinogen, bilirubin, blood/Hb
11. Changes in viral status over the study period: anti-HIV-1/2, HBsAg, anti-HBc, anti-HCV, anti-CMV, anti-HAV, anti-Parvovirus B19
12. Overall tolerability, AE monitoring, vital signs including body temperature

Measured at baseline, less than or equal to 30 minutes before and less than 5 minutes post plasmapheresis, 15 minutes and 2 hours post-transfusion, 24 hours and 7 days post-plasmapherese and 3 months after administration of IMP.

Completion date
01/04/2011

Eligibility

Key inclusion criteria
1. Signed written informed consent
2. Subject must be capable to understand and comply with all relevant aspects of the study protocol
3. Blood group AB
4. Healthy male or female subjects greater than or equal to 18 years of age
5. Female subject must have a negative pregnancy test (human chorionic gonadotropin [HCG]-based assay)
6. Female subject must apply sufficient methods of contraception
7. Subject must have no clinically relevant abnormalities in medical history and general physical examination
8. A standard health insurance must be in place for the subject

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnancy or lactation
2. Subject got tattoos within the last 3 months
3. Subject was treated therapeutically with FFP, blood or plasma-derived products in the

previous 6 months
4. Angiotensin converting enzyme (ACE)-inhibitors
5. Subject has a history of severe hypersensitivity to blood products or plasma protein
6. History of angiooedema
7. History of coagulation disorder or bleeding disorder and any known abnormality affecting coagulation, fibrinolysis or platelet function
8. Any other clinically relevant history of disease
9. Subject has clinically significant abnormal laboratory values
10. Subject has IgA deficiency
11. Seropositivity for hepatitis B surface antigens (HBsAg), hepatitis C virus (HCV), human immunodeficiency virus (HIV-1/2) antibodies
12. Symptoms of a clinically relevant illness within 3 weeks before Visit 2
13. Subject has a history of or a suspected drug or alcohol abuse
14. Participation in another clinical study within the past 4 weeks

Date of first enrolment
01/10/2010

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
Austria

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