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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
Registration date 10/01/2011	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 21/06/2011	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

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
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

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

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/10/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
4 to 6 (Study no longer recuiting: Last patient out on 28/03/2011)

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)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Octapharma AG (Switzerland)

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