

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

<b>Submission date</b> 22/12/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/01/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/06/2011	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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-plasmapheresis 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. Isoagglutinins (in case of a positive DAT)
6. Haematology: RBC count, WBC count, platelets, Hct, Hb
7. Standard safety lab (Clinical chemistry): sodium (Na<sup>+</sup>), potassium (K<sup>+</sup>), calcium (Ca<sup>2+</sup>), 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-plasmapheresis 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 recruiting: 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 angioedema
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

Vienna

Austria

1100

# Sponsor information

## Organisation

Octapharma AG (Switzerland)

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## Sponsor type

Industry

## Website

<http://www.octapharma.com>

## ROR

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

# 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

