

A comparison of safety, tolerability and efficacy of universal plasma (Uniplas™ LG) versus standard S/D plasma (Octaplas™ LG) in healthy volunteers: a randomised, double-blind, cross-over trial

Submission date 13/01/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/01/2009	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 23/03/2010	Condition category Other	☐ 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

Clinical Trials Information System (CTIS)
2008-004797-40

Protocol serial number
UNI-110

Study information

Scientific Title

Study objectives

Comparison of safety, tolerability, and efficacy of universal plasma (Uniplas™ LG) versus standard S/D plasma (Octaplas™ LG) in healthy volunteers.

As of 23/03/2010 this record was updated to include the actual end date of this trial. The initial anticipated end date of this trial was 31/12/2009.

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]) gave approval on the 20th November 2008 (ref: 395/2008)

Study design

Double-blind block-randomised cross-over phase I study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Safety/tolerability (haemolytic transfusion reaction) after transfusion of Uniplas™ LG

Interventions

The treatment day will start with plasmapheresis (600 ml) then transfusion of either Uniplas™ LG or Octaplas™ LG will be randomly assigned. Safety and tolerability will be assessed by clinical and laboratory parameters (haematology, complement activation, immune haematology). Efficacy will be measured by assessing coagulation factors. All these parameters will be collected before and immediately after plasmapheresis (PP), then 15 minutes, 2 hours, 24 hours and 7 days after end of investigational medicinal product (IMP) administration. Treatment sequence is either Uniplas™ LG or Octaplas™ LG or vice versa after a minimal wash out period of 1 month. The overall duration per subject will be 4 months including 3 months follow up and a treatment performed on 2 days.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

Plasma (Uniplas™ LG, Octaplas™ LG)

Primary outcome(s)

Haemoglobin (Hb), measured before and immediately after PP and at 15 minutes, 2 hours, 24 hours, 7 days and 3 months after end of IMP administration.

Key secondary outcome(s)

1. Parameters of haemolysis (haptoglobin, free Hb, indirect bilirubin)
2. Complement activation (CH50, C3c, C4)
3. Immune haematology (direct antiglobulin test [DAT])
4. Haematology (red blood cell [RBC] count, white blood cell [WBC] count, platelets, haematocrit [Hct])
5. Haemostatic parameters (activated partial thromboplastin time [aPTT], prothrombin time [PT], fibrinogen [Fbg], factor II [FII], factor V [FV], factor VII [FVII], factor VIII [FVIII], factor IX [FIX], factor X [FX], factor XI [FXI], protein S, plasmin inhibitor)
6. Changes in viral status over the study period (anti-HIV-1/2, HBsAg, hepatitis B core antigen [anti-HBc], anti-HCV, cytomegalovirus antigen [anti-CMV], hepatitis A virus antibody [anti-HAV], anti-Parvovirus B19)
7. Overall tolerability, vital parameters including body temperature, standard safety laboratory parameters

All primary and secondary endpoints will be measured before and immediately after PP and at 15 minutes/2 hours post-transfusion of IMP. The following extra timepoints will also be used:

1. 24 hours after end of IMP administration: haematology, DAT, complement and coagulation factors
2. 7 days after end of IMP administration: haematology, DAT and complement
3. 3 months after end of IMP administration: haematology, DAT, aPTT, PT, Fbg, and viral markers

Completion date

02/02/2010

Eligibility

Key inclusion criteria

1. Subject must be capable of understanding and complying with all aspects of the protocol
2. Signed informed consent
3. Fulfil criteria of plasma donors according to a standard questionnaire for blood components donors of the Department of Blood Group Serology and Transfusion Medicine
4. Healthy male or female volunteers greater than or equal to 18 years of age
5. Blood group A, B or AB
6. Women must have a negative pregnancy test (human chorionic gonadotropin [HCG]-based assay)
7. Women must have sufficient methods of contraception (e.g. intrauterine device, oral contraception)
8. Normal findings in medical history and physical examination unless the investigator considers an abnormality to be clinically irrelevant
9. Standard health insurance

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. Refusal to accept blood products
3. Tattoos within the last 3 months
4. Treatment with fresh frozen plasma (FFP) or blood products in the previous 6 months
5. Subjects with a history of hypersensitivity reaction in general or hypersensitivity to blood products or plasma protein in particular
6. History of angioedema
7. History of coagulation or bleeding disorder or any other known abnormality affecting coagulation, fibrinolysis or platelet function
8. Any other clinically relevant history of disease
9. Any clinically significant abnormal laboratory values including Immunoglobulin A (IgA) deficiency
10. Seropositivity for hepatitis B surface antigens (HBsAg), hepatitis C virus (HCV), human immunodeficiency virus 1/2 (HIV-1/2) antibodies
11. Symptoms of a clinically relevant illness within 3 weeks before the first trial day
12. Subjects with a history of, or suspected, drug or alcohol abuse
13. Subjects participating in another clinical study currently or during the past 1 month

Date of first enrolment

01/01/2009

Date of final enrolment

02/02/2010

Locations**Countries of recruitment**

Austria

Study participating centre

Oberlaaerstrasse 235

Vienna

Austria

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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