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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

Registration date
14/01/2009

Overall study status
Completed

Last Edited
23/03/2010

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
2008-004797-40

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/01/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

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 Immmunoglobulin 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
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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