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A comparative, open-label, randomised, cross-over phase I trial in healthy volunteers to investigate the relative efficacy, safety and tolerability of OctaplasLG™ versus Octaplas® SD

Submission date	Recruitment status	[ ] Prospectively registered
03/09/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/09/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/10/2009	Injury, Occupational Diseases, Poisoning	[ ] 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)
2009-012856-26

Protocol serial number
LAS-203

Study information

Scientific Title

Study objectives
Comparison of efficacy, safety and tolerability of OctaplasLG™ versus Octaplas® SD plasma in healthy volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (ethikkommission der med Uni Wien und des Allg Krankenhauses der Stadt Wien AKH) approved on the 15th July 2009 (ref: 460/2009)

Study design
Open-label block randomised cross-over phase I study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Safety/efficacy/tolerability of plasma products

Interventions
The treatment day will start with plasmapheresis (600 ml) then transfusion of either OctaplasLG™ or Octaplas® SD will be randomly assigned. Safety, efficacy and tolerability will be assessed by clinical and laboratory parameters (haematology, coagulation factors, haemostatic parameters, chemistry). 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 IMP administration. Treatment sequence is either OctaplasLG™ or Octaplas® SD or vice versa after a minimal wash out period of 1 month. The overall duration per subject will be 1.5 months and a treatment performed on 2 days.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
OctaplasLG™, Octaplas® SD

Primary outcome(s)

1. Coagulation factors
2. Activated partial thromboplastin time (aPTT), prothrombin time (PT), protein C

All primary and secondary endpoints will be measured before and immediately after PP and at 15 minutes, 2 hours and 24 hours post-transfusion of IMP. Haematology and clinical chemistry will be measured 7 days after end of IMP administration.

Key secondary outcome(s))
1. Haematology: red blood cell (RBC) count, white blood cell (WBC) count, platelets, haematocrit (Hct), haemoglobin (Hb), and plasmin inhibitor, Protein S
2. Clinical Chemistry: electrolytes, creatinine, alanine aminotransferase (ALAT), gamma-glutamyl transferase (GGT), total protein (TP)
3. Overall tolerability, vital parameters

All primary and secondary endpoints will be measured before and immediately after PP and at 15 minutes, 2 hours and 24 hours post-transfusion of IMP. Haematology and clinical chemistry will be measured 7 days after end of IMP administration.

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Subject must be capable of understanding and complying with all aspects of the protocol
2. Signed informed consent
3. Subject must be capable of understanding the plasmapheresis information sheet and sign it
4. Healthy male or female volunteers, aged 18 years or above
5. Women must have a negative pregnancy test (human chorionic gonadotrophin [HCG]-based assay)
6. Women must have sufficient methods of contraception (e.g. intrauterine device, oral contraception, etc.)
7. Subjects must have no clinically relevant abnormalities in medical history and general physical examination
8. 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. Tattoos within the last 3 months
3. Subject was treated therapeutically with FFP, blood or plasma derived products in the previous 6 months
4. Subjects have a hypersensitivity to blood products or plasma protein
5. History of angioedema
6. History of coagulation or bleeding disorder or any other known abnormality affecting coagulation, fibrinolysis or platelet function
7. Any clinically significant abnormal laboratory values
8. IgA deficiency
9. Seropositivity for HBs-Ag, HCV, HIV-1/2 antibodies
10. Symptoms of a clinically relevant illness within 3 weeks before the first trial day
11. Subjects with a history of, or suspected, drug or alcohol abuse
12. Subjects currently participating in another clinical study
13. Any IMP administration within the last 4 weeks

Date of first enrolment
01/07/2009

Date of final enrolment
01/10/2010

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