ISRCTN60768666 https://doi.org/10.1186/ISRCTN60768666

A sequential cohort study to compare tolerability and efficacy in patients receiving Octaplas® or Octaplas® LG

Submission date	Recruitment status	[ ] Prospectively registered
22/10/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/10/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/10/2008	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

Contact name
Dr Susanne Seeger

Contact details
Elisabeth-Selbert-Strasse 11
Langenfeld
Germany
40764

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LAS-201

Study information

Scientific Title

Study objectives
After implementation of a novel technology, Octaplas® LG has the same clinical safety and efficacy profile.

Ethics approval required
Old ethics approval format

Ethics approval(s)
As the procedures during this observational study do not interfere with the patient's usual treatment and monitoring of treatment, this study is not regarded as a clinical study as defined by EU Directive 2001/20/EC. Therefore approval by an Independent Ethical Committee and an Institutional Review Board is not required.

Study design
Non-interventional, sequential cohort, observational, open, prospective, multi-centre study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Plasma transfusion in normal clinical practice

Interventions
Before the first treatment with Octaplas® or Octaplas® LG, the physician will record the available baseline characteristics such as gender, date of birth, weight, blood group, diagnosis, and indication for use of plasma. Details of any plasma-derived blood or blood products given 24 hours before, during or within 48 hours after the treatment with Octaplas® or Octaplas® LG will also be documented.

Details of all Octaplas® or Octaplas® LG infusions will be recorded (date, times of start and end, batch number(s), number of bags, and transfusion volume). Whether the use of Octaplas® or Octaplas® LG is considered by the physician to be successful (Yes/No question) will be recorded, and the reason for the positive or negative assessment will be documented, together with any additional information that may be relevant. If any laboratory tests are done to assess the therapeutic effect of Octaplas® or Octaplas® LG, including but not limited to the international

normalised ratio (INR), these will also be recorded. No investigations must be initiated for the purpose of this non-interventional trial. Details of any adverse drug reactions will also be recorded.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Octaplas®, Octaplas® LG

Primary outcome measure
To observe the usage of the current product Octaplas® and the product with an additional chromatography step Octaplas® LG under normal clinical conditions to ascertain if there are any differences in patients outcomes with respect to effectiveness and tolerability.

The effectiveness of Octaplas® and Octaplas® LG will be an objective assessment by the physician based on clinical or laboratory parameters relevant for the indication of whether the use of the product was successful or not. The tolerability will be evaluated on the basis of the number, nature, type and severity of adverse drug reactions (ADR). At the end of the study methods of descriptive statistics will be used to compare the effectiveness and tolerability of Octaplas® and Octaplas® LG.

Secondary outcome measures
No secondary outcome measures.

Overall study start date
01/08/2008

Completion date
30/06/2009

Eligibility

Key inclusion criteria
Patients of any age who require a transfusion with Octaplas®/Octaplas® LG are eligible for study enrolment.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants

Key exclusion criteria
1. Known relative contraindications such as latent or apparent cardial decompensation, hypervolaemia, hyperhydration, lung oedema and selective serum IgA deficiency
2. Known absolute contraindications such as hypersensitive against plasma proteins and antibodies against IgA

Date of first enrolment
01/08/2008

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Germany

Study participating centre
Elisabeth-Selbert-Strasse 11
Langenfeld
Germany
40764

Sponsor information

Organisation
Octapharma GmbH (Germany)

Sponsor details
Elisabeth-Selbert-Strasse 11
Langenfeld
Germany
40764

Sponsor type
Industry

ROR
https://ror.org/002k5fe57

Funder(s)

Funder type
Industry

Funder Name
Octapharma GmbH (Germany)

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