

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

Submission date 22/10/2008	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/10/2008	Overall study status Completed	☐ Protocol
Last Edited 30/10/2008	Condition category Injury, Occupational Diseases, Poisoning	☐ 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

Contact name

Dr Susanne Seeger

Contact details

Elisabeth-Selbert-Strasse 11
Langenfeld
Germany
40764

Additional identifiers

Protocol serial number

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.

Primary study design

Observational

Study design

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

No secondary outcome measures.

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Known relative contraindications such as latent or apparent cardiac 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)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Octapharma GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration