

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

<b>Submission date</b> 22/10/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/10/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 30/10/2008	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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 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)

**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