

# Tolerability of the intravenous immunoglobulin Octagam® 10%

<b>Submission date</b> 26/11/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/11/2022	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
GAM10-05

## Study information

**Scientific Title**  
Tolerability of the intravenous immunoglobulin Octagam® 10%

**Study objectives**

Octagam® 10% is well tolerated in routine clinical use in the treatment of primary or secondary immunodeficiencies or in the immunomodulation of autoimmune diseases.

### **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 is not required.

### **Study design**

Non-interventional prospective multi-centre observational cohort study

### **Primary study design**

Observational

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Primary or secondary immunodeficiencies, immunomodulation in autoimmune diseases

### **Interventions**

Treatment with Octagam® 10% will be documented. This includes data about the patient's disease, age, gender, weight, concomitant medication or illness. For each application, the date and duration of infusion, dose, batch number(s) and the absence or occurrence of an adverse drug reaction (ADR) will be recorded. In case of an ADR, additional detailed information about the reaction will be recorded. If available, laboratory data about the efficacy of treatment should also be documented. No investigations must be initiated for the purpose of this non-interventional trial.

The number of treatments with Octagam® 10% for each patient cannot be defined due to the different indications where it is used. Therefore some patients will be treated and observed for a few weeks and others for several months or years. For this reason, there are no specified timepoints for the outcomes of this trial.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Octagam® 10%

### **Primary outcome(s)**

To observe the tolerability of Octagam® 10% in different indication groups in routine clinical practice

**Key secondary outcome(s)**

Data about the efficacy of Octagam® 10%

**Completion date**

14/09/2013

**Eligibility****Key inclusion criteria**

Patients of any age and gender who receive treatment with Octagam® 10%

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

All

**Sex**

All

**Key exclusion criteria**

Patients with known contraindications to Octagam® 10%

**Date of first enrolment**

15/09/2008

**Date of final enrolment**

14/09/2013

**Locations****Countries of recruitment**

Germany

**Study participating centre**

Octapharma GmbH

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

Not provided at time of registration

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	post-authorisation safety analysis	01/05/2018		Yes	No
<a href="#">Results article</a>		08/03/2018	14/11/2022	Yes	No