

The tolerability of Octagam® 5% and Octagam® 10%

Submission date 01/09/2011	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 25/10/2011	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 14/11/2022	Condition category Haematological Disorders	☐ Individual participant data

Plain English summary of protocol

Background and study aims?

Several kinds of illnesses (autoimmune diseases and immune deficient conditions) are treated with Octagam. Octagam is a solution that contains human antibodies, also called immunoglobulins. In this study the data about the treatment with Octagam will be collected to analyse how often and which side effects might occur when treated with Octagam in regular praxis as prescribed by your doctor.

Who can participate?

Only the doctor can decide which disease can be treated with Octagam. People of any age and any gender are welcome to participate.

What does the study involve?

The study collects only data and therefore the doctor might ask you some questions regarding previous diseases or treatments. There will be no special investigations or procedures due to the study. The treatment with Octagam will be regular as prescribed by your doctor without the study.

What are the possible benefits and risks of participating?

All information collected in the course of the treatment with Octagam may make an important scientific contribution, in particular to other patients suffering from the same or similar conditions that may also be treated with Octagam. Octagam is a registered product, the side effects are described in the package insert.

Where is the study run from?

About 1000 patients will participate in this study, which will be performed in several countries around the world (e.g. Austria, France, UK, Brazil, and other). In the USA there will be a related study.

When is study starting and how long is it expected to run for?

The study is planned to start in September 2011. The overall study duration will be approximately 3 years.

Who is funding the study?

A Swiss company called Octapharma, who is producing Octagam, is organising and funding this study.

Who is the main contact?

Dr Daniel Svorc and Dr Stefan Wietek
daniel.svorc@octapharma.com

Contact information

Type(s)

Scientific

Contact name

Prof Franz Fazekas

Contact details

Auenbruggerplatz 22
Graz
Austria
8036

Additional identifiers

Protocol serial number

GAM10-06

Study information

Scientific Title

A non-interventional study on the tolerability of Octagam® 5% and Octagam® 10%

Acronym

GammaTrack

Study objectives

Re-establish the tolerability profile of Octagam® seen over the last 15 years before the suspension of the marketing authorisations for Octagam® (human normal immunoglobulin 5% and 10%) by the European Medicines Agency.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Medical University Graz, Austria, 25/07/2011 ref: 23-474 ex 10/11

Primary study design

Observational

Study design

Prospective uncontrolled multi-centre multi-national non-interventional study

Study type(s)

Screening

Health condition(s) or problem(s) studied

Any indication, age, or treatment regimen in which Octagam is prescribed

Interventions

The individual observation period for one patient is not limited, PID patients should be observed for a minimum of 10 months, if possible.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Incidence of adverse drug reactions (ADRs)

Key secondary outcome(s)

Efficacy of treatment

Completion date

01/06/2014

Eligibility**Key inclusion criteria**

All patients treated with Octagam at a participating site.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/09/2011

Date of final enrolment

01/06/2014

Locations**Countries of recruitment**

United Kingdom

Austria

Brazil

France

Russian Federation

Study participating centre

Auenbruggerplatz 22

Graz

Austria

8036

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

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?
Results article	post-authorisation safety analysis	01/05/2018		Yes	No
Results article		08/03/2018	14/11/2022	Yes	No