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

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

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
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Austria
8036

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Incidence of adverse drug reactions (ADRs)

Secondary outcome measures
Efficacy of treatment

Overall study start date
01/09/2011

Completion date
01/06/2014

Eligibility

Key inclusion criteria
All patients treated with Octagam at a participitating site.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1000

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
Austria

Brazil

France

Russian Federation

United Kingdom

Study participating centre
Auenbruggerplatz 22
Graz
Austria
8036

Sponsor information

Organisation
Octapharma AG (Switzerland)

Sponsor details
c/o Dr Daniel Svorc
Seidenstrasse 2
Lachen
Switzerland
8853

Sponsor type
Industry

Website
http://www.octapharma.com/en.html

ROR
https://ror.org/002k5fe57

Funder(s)

Funder type
Industry

Funder Name
Octapharma AG (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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