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Tolerability and safety of octagam® 5%, octagam® 10% and panzyga®

Submission date	Recruitment status	[X] Prospectively registered
15/11/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/11/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/11/2018	Haematological Disorders	

Plain English summary of protocol

Background and study aims
octagam® 5%, octagam® 10% and panzyga® are solutions that contain human immunoglobulins (antibodies) and are given through the vein (intravenously). They are used for the treatment of congenital or acquired antibody deficiency diseases, immune modulation or in bone marrow transplantation. This study aims to expand our knowledge and experience in the safe use of these medicines.

Who can participate?
Patients who receive treatment with octagam® 5%, octagam® 10% or panzyga®.

What does the study involve?
This study does not have any procedures (interventions). Only information about treatment with octagam® 5%, octagam® 10% or panzyga® in routine clinical practice is collected. The treatment with octagam® 5%, octagam® 10% or panzyga® is the same as if they were prescribed outside of the study.

What are the possible benefits and risks of participating?
This is a safety study and all collected information about the observed medicines will make an important scientific contribution in keeping or even improving the high levels of tolerability and safety of octagam® 5%, octagam® 10% or panzyga®. These are registered products and the side effects are described in the package insert.

Where is the study run from?
About 200 study centres from all over Germany are participating in this study. Recruitment of participating physicians is still ongoing.

When is the study starting and how long is it expected to run for?
January 2014 to December 2019

Who is funding the study?
Octapharma GmbH (Germany).

Who is the main contact?
Mr Christian Lietz
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Contact information

Type(s)
Scientific

Contact name
Mr Christian Lietz

Contact details
Elisabeth-Selbert-Strasse 11
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Germany
40764

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GAM-33

Study information

Scientific Title
Non-interventional safety study on the tolerability and safety of octagam® 5%, octagam® 10% and panzyga®

Study objectives
octagam® 5%, octagam® 10% or panzyga® are well tolerated in the treatment of primary or secondary immunodeficiencies or in the immunomodulation of autoimmune diseases, in routine clinical use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Non-interventional prospective multi-centre safety study

Primary study design

Observational

Secondary study design
Multi-centre

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Autoimmune diseases

Interventions
Treatment with octagam® 5%, octagam® 10% or panzyga® 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.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
1. octagam® 5% 2. octagam® 10% 3. panzyga®

Primary outcome measure
The physician will have to fill out CRFs and send them back in a bunch of six subsequent documented treatments including one form which describes the progress of the treatment over this period. The individual observation period is not limited.

Secondary outcome measures
Quality of life will be evaluated by using the SF-36 health survey

Overall study start date
01/01/2014

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Patients of any age and gender, who receive treatment with octagam® 5%, octagam® 10% or panzyga®

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
5000

Key exclusion criteria
Patients with known contraindications as specified in the Summary of Product Characteristics (SPC)

Date of first enrolment
01/02/2014

Date of final enrolment
30/11/2019

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2016		Yes	No