

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

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

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

Protocol serial number
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

Primary study design
Observational

Study design
Non-interventional prospective multi-centre safety study

Study type(s)
Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

All

Sex

All

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)

ROR

<https://ror.org/002k5fe57>

Funder(s)**Funder type**

Industry

Funder Name

Octapharma GmbH (Germany)

Results and Publications

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