ISRCTN58800347 https://doi.org/10.1186/ISRCTN58800347

Tolerability of the intravenous immunoglobulin Octagam® 10%

Submission date	Recruitment status	[_] Prospectively registered
26/11/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/12/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/11/2022	Haematological Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Anette Debes

Contact details
Elisabeth-Selbert-Str. 11
Langenfeld
Germany
40764
-
anette.debes@octapharma.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Secondary outcome measures
Data about the efficacy of Octagam® 10%

Overall study start date
15/09/2008

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

Age group
All

Sex
Both

Target number of participants
600

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)

Sponsor details
Elisabeth-Selbert-Str. 11
Langenfeld
Germany
40764
-
info@octapharma.de

Sponsor type
Industry

Website
http://www.octapharma.de/

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
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