

Clinical study to evaluate the efficacy and safety of Octagam 5% in patients with Primary Immunodeficiency diseases (PID)

Submission date 18/09/2012	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 15/10/2012	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 15/10/2012	Condition category Haematological Disorders	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims:

The study will assess if Octagam 5% prevents serious bacterial infections.

Who can participate?

Patients aged between 18 and 75 years with immunodeficiency.

What does the study involve?

The patients will receive an examination at the start of the study and then receive five or six infusions of Octagam 5% over a period of up to 20 weeks. Participants will be asked to give a small amount of blood for assessment .

What are the possible benefits and risks of participating?

Patients health condition will be assessed very thoroughly and in shorter intervals than normal. There are no known risks of participating.

Where is the study run from?

Octapharma AG in Switzerland a pharmaceutical company producing and selling products developed from blood plasma.

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

Study is starting in June 2012 and expected end is in October 2013

Who is funding the study?

Octapharma AG, Switzerland

Who is the main contact?

Dr Eva Turpel-Kantor

Contact information

Type(s)

Scientific

Contact name

Dr Eva Turpel Kantor

Contact details

Octapharma

Vienna

Austria

1100

Additional identifiers

Protocol serial number

GAMr-29

Study information

Scientific Title

Prospective, open-label, non-controlled, multicenter, phase III clinical study to evaluate the pharmacokinetics, safety and efficacy of Octagam 5% in patients with Primary Immunodeficiency Diseases

Acronym

GAMr 29

Study objectives

The pharmacokinetic of Octagam 5% ("double-processed" Octagam) and efficacy in preventing serious bacterial infections is as to be expected for a compound of this class.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Polish Ministry of Health, 24 September 2012 ref: MZOKB-078-262-1/EO

Primary study design

Interventional

Study design

Prospective open-label non-controlled multicenter phase III study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Primary Immunodeficiency diseases (PID)

Interventions

Two multiple dose intravenous Octagam 5% regimens (every 3 weeks or every 4 weeks, continuing the patients pre-study infusion interval) for 6 or 5 Octagam infusions for patients on a 3-week or 4-week schedule, respectively .

The investigational medicinal product (IMP) name is Octagam 5%, a human immunoglobulin (Ig) solution with 5% protein content for intravenous administration.

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

The primary endpoint is the PK profile of Octagam with respect to total IgG, IgG subclasses

Key secondary outcome(s)

The following parameters will be used in the safety and tolerability assessment of the treatment:

1. Vital signs
2. Physical examination
3. AEs
4. Laboratory parameters

Completion date

15/07/2013

Eligibility**Key inclusion criteria**

1. Age between 18 years and 75 years
2. Primary immunodeficiency syndromes with significant component hypogamma-globulinaemia or antibody deficiency
3. Previously treated with a commercial IVIG every 2128 days for at least 6 infusion intervals at a constant dose between 200 and 800 mg/kg body weight
4. Availability of the IgG trough levels of the 2 previous infusions before enrolment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Acute infection
2. Known history of adverse reactions to IgA in other products
3. Exposure to blood or any blood product, other than commercially available IVIG, within the past 3 months prior to enrolment
4. Congestive heart failure NYHA class III or IV
5. Non-controlled arterial hypertension
6. History of deep vein thrombosis
7. Known HIV, HCV, or HBV infection

Date of first enrolment

15/07/2012

Date of final enrolment

15/07/2013

Locations

Countries of recruitment

Austria

Czech Republic

Study participating centre

Octapharma

Vienna

Austria

1100

Sponsor information

Organisation

Octapharma (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

IPD sharing plan summary

Not provided at time of registration