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

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

## 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

# Study design

Prospective open-label non-controlled multicenter phase III study

# Primary study design

Interventional

## 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

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes