

Clinical study to evaluate the efficacy and safety of Octagam 10% in Primary Immune Thrombocytopenia (ITP)

Submission date 06/07/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/07/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/09/2014	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Administration of antibodies into a vein (intravenous immunoglobulin [IVIG]) has proved to be useful in a variety of clinical conditions. In patients suffering from immune thrombocytopenia (ITP), several studies have shown IVIG to be effective in increasing platelet counts (PC) to prevent or control bleeding. In this study we will assess whether Octagam 10% similarly corrects (i.e., increases) the platelet count compared with normal IVIG.

Who can participate?

Patients aged 18-65 with chronic Primary Immune Thrombocytopenia (ITP) of at least 12 months duration.

What does the study involve?

All patients will receive two infusions of Octagam 10% for two consecutive days. Vital signs will be monitored at the start of the infusion, at least once during the infusion and about 1 hour after the end of the infusion. Over the study period of 22 days participants will be asked to give a small amount of blood for assessment of platelet count and safety parameters.

What are the possible benefits and risks of participating?

Patients will receive highly purified antibodies for a quick increase in platelet count. Due to the 10% concentration, this may shorten the infusion time compared to commercial IVIG treatments the patient previously received. The product underwent two times some of the production steps in which impurities and viruses are eliminated. During this study the patients health condition will be assessed very thoroughly and in shorter intervals than normal. Even though the patient may not receive any personal benefit, participation in this study will benefit society as a whole by providing new information about the treatment of ITP and thus improving quality of life to those who suffer the condition. The risks of IVIG administration are well documented. In general, the incidence of adverse events associated with IVIG tends to increase with the rate of infusion, and thus the recommended dosage, infusion rates, and monitoring procedures should be adhered to.

Where is the study run from?

The study has been set up by a pharmaceutical company producing and selling products developed from blood plasma, called Octapharma AG (Switzerland).

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

It is anticipated that recruitment will start in August 2012. Participants will be enrolled in the study for a period of almost 2 years or until the 30th patient has completed the study. The study is expected to be completed in March 2014.

Who is funding the study?

Funding has been provided by Octapharma AG (Switzerland).

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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13353

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

GAMr-30

Study information

Scientific Title

Prospective, open-label, non-controlled, multicenter, phase III clinical study to evaluate the efficacy and safety of Octagam 10% in Primary Immune Thrombocytopenia

Study objectives

The efficacy of Octagam 10% ('double-processed' Octagam) in correcting the platelet count (PC) is to be expected for a compound of this class.

On 10/04/2013 the following changes were made to the trial record:

1. The anticipated start date was updated from 11/07/2012 to 30/08/2012.
2. The anticipated end date was updated from 30/06/2014 to 29/03/2013.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics Committee of the Institute for Clinical and Experimental Medicine and Thomayer Hospital, Prague, Czech Republic, 11/04/2012, ref: 561/12 (M 12-19)
2. Independent Bioethics Committee for Scientific Research of the Medical University of Gdansk, Gdansk, Poland, 10/05/2012, ref: NKBBN/166/2012
3. Ethik-Kommission des Landes Berlin, Landesamt für Gesundheit und Soziales, Berlin, Germany, 18/06/2012, ref: 12/0175 ZS EK 15
4. Comisia Națională de Etică pentru Studiul Clinic al Medicamentului, București, Romania, 06/06/2012, ref: 1255; 1936

Study design

Prospective open-label non-controlled multicenter phase III study.

Primary study design

Interventional

Secondary study design

Case-control study

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

Primary Immune Thrombocytopenia (ITP).

Interventions

Administration of intravenous immunoglobulin (IVIG). One treatment arm: treatment with Octagam 10% at two consecutive days at a dosage of 1 g/kg/day.
Laboratory assessments.

Intervention Type

Other

Phase

Phase III

Primary outcome measure

1. Platelet count and the increase in platelets to and the maintenance of specific thresholds
2. Number and percentage of patients with response (R), complete response (CR), no response (NR) and loss of response as well as time to response and duration of response will be presented descriptively to facilitate the comparison of the study results to data from the literature

Secondary outcome measures

Evaluate the safety of Octagam 10%

Overall study start date

30/08/2012

Completion date

29/03/2013

Eligibility

Key inclusion criteria

1. Age of ≥ 18 years and ≤ 65 years
2. Confirmed diagnosis of chronic primary ITP (threshold PC less than $100 \times 10^9/L$) of at least 12 months duration
3. Platelet count of $< 30 \times 10^9/L$ with or without bleeding manifestations

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30

Key exclusion criteria

1. Thrombocytopenia secondary to other diseases (such as AIDS or SLE) or drug-related thrombocytopenia
2. Administration of IVIG, anti-D or thrombopoietin receptor agonists or other platelet enhancing drugs (including immunosuppressive or other immunomodulatory drugs) within 3 weeks before enrolment
3. Unresponsive to previous treatment with IVIG or anti-D immunoglobulin

4. Severe liver or kidney disease (ALAT 3x > upper limit of normal, creatinine >120 µmol/L)
5. Patients with risk factors for TEEs in whom the risks outweigh the potential benefit of Octagam treatment

Date of first enrolment

30/08/2012

Date of final enrolment

29/03/2013

Locations

Countries of recruitment

Bulgaria

Czech Republic

Germany

Poland

Romania

Study participating centre

Universitätsklinikum Charité

Berlin

Germany

13353

Sponsor information

Organisation

Octapharma AG (Switzerland)

Sponsor details

Seidenstrasse 2

CH-8853 Lachen

Lachen

Switzerland

CH-8853

Sponsor type

Industry

Website

<http://www.octapharma.com/>

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Octapharma AG (Switzerland)

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