ISRCTN78894548 https://doi.org/10.1186/ISRCTN78894548

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

Registration date
12/07/2012

Overall study status
Completed

Last Edited
29/09/2014

Condition category
Haematological Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
Dr Stefan Wietek
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 Nationalã de Eticã pentru Studiul Clinic al Medicamentului, Bucureºti, Romania, 06/06 /2012, ref: 1255; 1936

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 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(s)
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

Key secondary outcome(s))
Evaluate the safety of Octagam 10%

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 100x10^9/L) of at least 12 months duration
3. Platelet count of <30x10^9/L with or without bleeding manifestations

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
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Sponsor information

Organisation
Octapharma AG (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