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Clinical study to evaluate the efficacy and safety of immunoglobulin intravenous (human) 10% (NewGam) in Primary Immune Thrombocytopenia

Submission date
20/02/2013

Recruitment status
No longer recruiting

Registration date
27/02/2013

Overall study status
Completed

Last Edited
10/04/2019

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
In this study, it will be assessed, whether NewGam [immunoglobulin intravenous (human)] corrects (i.e. increases) the platelet count.

Who can participate?
Patients with confirmed diagnosis of chronic Primary Immune Thrombocytopenia (ITP) of at least 12 months duration, age >=18 years and <=65 years, and a platelet count of <20x10 exp9/L with or without bleeding manifestations.

What does the study involve?
Beside examination at study start all patients will receive two intravenous infusions of NewGam at two consecutive days. Over a period of 63 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?
Patient will receive NewGam for a quick increase in platelet count. During this study the patients health condition will be assessed in shorter intervals than normal.
The most common side effects when people take intravenous (IV) immunoglobulin are headache, chills, back pain, chest pain, myalgia, fever, cutaneous reactions, fatigue, various minor allergic and hypersensitivity type of reactions, hot flushes and nausea.

Where is the study run from?
The study has been set up by Octapharma AG, a pharmaceutical company.

When is study starting and how long is it expected to run for?
Study started in June 2011 and expected to end in June 2013.

Who is funding the study?
Octapharma AG (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01349790

Protocol serial number
NGAM-02

Study information

Scientific Title
Prospective, open-label, non-controlled, multicenter, phase III clinical study to evaluate the efficacy and safety of immunoglobulin intravenous (human) 10% (NewGam) in Primary Immune Thrombocytopenia

Study objectives
To assess the efficacy of NewGam in correcting the platelet count.

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, 11.05.2011, ref: 710/11 (M11-25)

2. Ethics Committee for Multicentre Trials, 8 Damyan Gruev Str., 1303 Sofia, Bulgaria, 3.10.2011, KE-107/22.06.2011
3. Comité de Protection des personnes Sud Méditérrannée I, Institut Paoli Calmettes, 232 Boulevard Ste Marguerite, 13009 Marseille; France; 30. 01. 2012, Ref: 11 47
4. Ethik-Kommission des Landes Berlin Landesamt für Gesundheit und Soziales Berlin, Fehrbelliner Platz 1, 10707 Berlin; 07.09. 2011, 11/0218 ZS EK
5. Independent Bioethical Committee for Scientific Research at Medical University in Gdañsk, 3a M. Sk³odowskiej - Curie str.; 80-210 Gdañsk, 07.07.2011
6. National Ethics Committee, 48 Av. Sanatescu St., District 1, Bucharest, Romania, 20.07.2011
7. Ministry of Healthcare and Social Development, Ethics Committee, 8, Petrovskiy avenue, 127051, Moscow, Russia, 24.08.2011
8. Central Ethics Commitee, 03680 Kiev, st. Narodnogo Opolchenia, 5, Ukraine, 5.12-1035/KE, 07.09.2011
9. lnstitutional Ethics committee for Sahyadri Hospitals, 30C, Erandawane, Karve Road, Pune 411004, India, 18.08.2011

Study design
Prospective open-label non-controlled multicenter phase III clinical study

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Primary Immune Thrombocytopenia (ITP)

Interventions
All patients will receive 1 g/kg/day NewGam by intravenous infusion for 2 consecutive days, for a total of 2 g/kg.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Immunoglobulin intravenous (human) 10% (NewGam)

Primary outcome(s)
The primary efficacy measure is defined as an increase in platelets to atleast 50x109/L within 7 days after the first infusion, i.e. by study Day 8 (at least once prior to Day 9).

Key secondary outcome(s))
Additional response rates will be calculated on basis of an alternative definition for response and for additionally defined criteria for complete response and loss of response.

Completion date
30/06/2013

Eligibility

Key inclusion criteria
1. Age of >=18 years years and <=65 years
2. Confirmed diagnosis of chronic primary ITP of at least 12 months duration (diagnosed with threshold platelet count less than 100x109/L)
3. Platelet count of <=20x10exp9/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 Acquired Immunodeficiency Syndrome [AIDS] or systemic lupus erythematosus [SLE]) or drug-related thrombocytopenia.
2. Administration of intravenous immunoglobulin (IGIV), anti-D or thrombopoetin receptor agonists or other platelet enhancing drugs (incl. immunosuppressive or other immunomodulatory drugs) within 3 weeks before enrollment
3. Unresponsive to previous treatment with IGIV or anti-D immunoglobulin.
4. Severe liver or kidney disease (alanine aminotransferase [ALAT] 3x > upper limit of normal, creatinine >120 µmol/L).
5. Patients with risk factors for thromboembolic events in whom the risks outweigh the potential benefit of NewGam treatment.

Date of first enrolment
30/06/2011

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
Bulgaria

Czech Republic

France

Germany

India

Poland

Romania

Russian Federation

Ukraine

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019	10/04/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes