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To investigate the ability of the Heidelberg Assay Panel (HAP) score to predict responders to Octagam 5% in patients with early relapsing multiple sclerosis

Submission date
04/06/2013

Recruitment status
No longer recruiting

Registration date
26/06/2013

Overall study status
Completed

Last Edited
21/06/2019

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Multiple sclerosis is a condition which affects the brain and/or spinal cord, causing problems with vision, arm or leg movement, sensation or balance. The aim of this study is to assess whether a blood test called the Heidelberg Assay Panel can be used to predict which patients with early relapsing multiple sclerosis respond to treatment with the drug Octagam.

Who can participate?
Patients aged 18 or over with early relapsing multiple sclerosis

What does the study involve?
Participants are pre-classified using the Heidelberg Assay Panel as either responders or non-responders to Octagam, and are randomly allocated to be treated with either Octagam or interferon-beta/glatiramer acetate. Participants in all four groups receive either treatment over a period of up to 116 weeks, and are asked to give a small amount of blood for further tests, fill in a questionnaire and undergo some nervous-system-related tests. The multiple sclerosis relapse rates are compared between the four groups.

What are the possible benefits and risks of participating?
The benefits are that the participants' health is monitored very thoroughly and more frequently than normal. There are no known risks of participating.

Where is the study run from?
Octapharma AG (Switzerland)

When is study starting and how long is it expected to run for?
June 2013 to September 2016

Who is funding the study?
Octapharma AG (Switzerland)

Who is the main contact?
Ms Barbara Pyringer

Contact information

Type(s)
Scientific

Contact name
Ms Barbara Pyringer

Contact details
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Additional identifiers

Clinical Trials Information System (CTIS)
2012-005086-12

Protocol serial number
GAM-27

Study information

Scientific Title
Prospective, multicentre, rater-blinded, active-controlled, randomised, 4-arm parallel-group phase IIIb study to investigate the ability of the HAP score to predict responders to Octagam 5% in patients with early relapsing multiple sclerosis

Acronym
PREDICT

Study objectives
The HAP score enables to accurately predict responders to Octagam 5% treatment in patients with early relapsing multiple sclerosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Innsbruck EC, 06/06/2013, ref: UN5107

Primary study design
Interventional

Study design
Prospective multicentre rater-blinded active-controlled randomised four-arm parallel-group study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Early relapsing multiple sclerosis (MS)

Interventions
Group 1: Pre-classified as responders, receives the investigational medicinal product (IMP), Octagam 5%, 0.6 g/kg, which is a human immunoglobulin (Ig) solution with 5% protein content. This is administered intravenously (iv) in 4 week intervals.
Group 2: Pre-classified as responders receives the comparator product (Control): either interferon-beta subcutaneous (IFN-β sc) or glatiramer acetate (GA) according to the manufacturers prescribing information.
Group 3: Pre-classified as non-responders receives Octagam 5%. This is administered intravenously (iv) in 4 week intervals.
Group 4: Pre-classified as non-responders receives the comparator product (Control): either interferon-beta subcutaneous (IFN-β sc) or glatiramer acetate (GA) according to the manufacturers prescribing information
Duration of treatment in study is 104 weeks plus a follow-up period of 12 weeks.
The HAP score will be measured centrally in a designated lab.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Octagam 5%

Primary outcome(s)
The primary endpoint is superiority with regard to decreased Annualised Relapse Rate (ARR) of Octagam 5% treatment in patients pre-classified as predicted responders compared to predicted non-responders.
Neurological monitoring at each visit and Expanded Disability Status Scale (EDSS) and Multiple Sclerosis Functional Composite (MSFC) score at visits week 24, 52, 80, 104, 116

Key secondary outcome(s)
1. ARR of Octagam 5% treatment compared to active control
2. ARR of comparator treatment compared between predicted responders and non-responders to Octagam 5% treatment
3. Compare ARR of predicted responder to Octagam 5% treatment with both IMP treatment arms combined
4. Percentage of actual responders and non-responders in the 21-month period between 3

months after the first study treatment (run-in phase) and the end of treatment period at month 24

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Patients aged 18 years or above
2. Early diagnosis of the relapsing form of MS (≤ 5years) according to the revised McDonald criteria (1-3)
3. Patients who are at least 3 months on stable dosage of either IFN-β sc or GA and who did not receive the other first-line therapy before
4. Kurtzke Expanded Disability Status Scale (EDSS) less or equal to 3.5
5. Patients who experienced at least one medically confirmed relapse during the last 12 months or at least two such relapses in the last 24 months prior to study entry (but not within 30 days between last steroid treatment of relapse and start of screening); subjects who relapse during the screening phase can be re-screened, once the relapse has resolved but earliest 30 days after the end of relapse treatment with steroids) or at least 1 T1 Gd+ lesion at screening

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
174

Key exclusion criteria
1. Patients who have received treatment with immunoglobulins for any reason in the last 6 months
2. Patients who have received immunosuppressive treatments (e.g., azathioprine, mitoxantrone, cyclophosphamide) for any reason, in the past
3. Treatment with steroids (oral or parenteral, long-term, i.e. 30 days or more, not intermittent or burst, daily, ≥0.15 mg of prednisone or equivalent/kg/day) except relapse treatment with corticosteroids
4. Patients who have received monoclonal antibody therapy with natalizumab in the last 12 months
5. Patients who have ever received monoclonal antibody therapy with alemtuzumab,

daclizumab, or ocrelizumab
6. Patients with severe renal function impairment as defined by serum creatinine values >120 µmol/L
7. Patients with known intolerance to homologous immunoglobulins, especially immunoglobulin A (IgA) deficiency (when the patient has antibodies against IgA)
8. Patients with a body weight higher than or equal to120 kg
9. Patients with a history of anaphylaxis after previous transfusions of blood or blood products
10. Patients for whom MRI is contraindicated or who are allergic to gadolinium (not complete)

Date of first enrolment
30/06/2013

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Austria

Bulgaria

Germany

Hungary

Russian Federation

Study participating centre
Octapharma Pharmazeutika Produktionsges.m.b.H
Vienna
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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?
Basic results			21/06/2019	No	No