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A prospective, multicentre, open label, exploratory study to investigate the ability of the Heidelberg assay panel and the B-Cell /antibody response panel to predict the clinical effect of Octagam® 5% in subjects with relapsing/remitting multiple sclerosis

Submission date	Recruitment status	[X] Prospectively registered
18/03/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/03/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/04/2013	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Stefan Wietek

Contact details
Octapharma PPG
Vienna CR&D Office
Oberlaaer Str. 235
Vienna
Austria
1100
+43 (0)1 61032 1778
stefan.wietek@octapharma.com

Additional identifiers

Protocol serial number

GAM-25

Study information

Scientific Title

Study objectives
To find a panel of laboratory parameters which might be able to predict the clinical outcome of treatment of patients with relapsing-remitting multiple sclerosis (MS) with Octagam®.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. EC Medical University of Innsbruck (Austria) - includes approval for Linz and Klagenfurt; approval received on the 9th January 2009 and final approval for additional study materials received on 22nd January 2009
2. EC Heidelberg (Germany) - includes approval for study sites at Heidelberg, Asbach, Berlin, Hamburg, Regensburg, Rostock; approval received on the 31st March 2009

Primary study design
Interventional

Study design
Prospective exploratory open label multicentre phase II trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
Octagam® 5% (12 infusions 0.4 g/kg every 4 weeks).

Intervention Type
Other

Phase
Phase II

Primary outcome(s)
A panel of lab parameters (components of cells of the immune system, serum proteins, gene expression, single nucleotide polymorphism [SNP] analysis) will be analysed at baseline, 12 - 24 hours after end of the first infusion, and 24 and 48 weeks after the first Octagam® administration and the clinical course of the disease will be monitored by relapse activity, EDSS and Multiple Sclerosis Functional Composite (MSFC) at predefined time points. Statistical

analysis will test whether any of the lab parameters of the HAP panel or the B-cell antibody response panel might be able to predict the clinical outcome observed following Octagam® 5% treatment. The proportion of subjects clinically responding to Octagam® 5% will be determined.

Key secondary outcome(s)
Lesion load in brain MRI imaging (T2 weighted, T1 weighted, Gd-enhancing lesion load) after treatment will be compared to lesion load before treatment.

Completion date
20/09/2010

Eligibility

Key inclusion criteria
1. Subjects aged greater than or equal to 18 years, either sex
2. Multiple sclerosis (MS) according to the revised McDonald criteria
3. Relapsing-remitting form of MS
4. First-line disease modifying treatments (interferon-beta [IFN-beta] or glatiramer acetate) are contraindicated or not tolerated
5. Kurtzke's Expanded Disability Status Scale (EDSS) between 0 and 3.5 (0 to less than 3.5)
6. Subjects who experienced at least one relapse during the last 12 months or at least two relapses in the last 24 months prior to study entry
7. Freely given, fully informed written consent obtained from subject

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Subjects who have received treatment with immunoglobulins for any reason previously
2. Subjects who have received immuno-suppressive treatments (e.g. azathioprine, mitoxantrone, cyclophosphamide) for any reason previously except relapse treatment with corticosteroids
3. Subjects who have received disease modifying first-line treatments with IFN-beta during the last 8 weeks or with glatiramer acetate during the last 16 weeks
4. Subjects who have received any monoclonal antibody therapies (e.g. natalizumab) previously
5. Subjects who had a relapse within 3 months prior to study entry
6. Subjects with severe renal function impairment as defined by serum creatinine values greater than 24 mg/l
7. Subjects with known intolerance to homologous immunoglobulins, especially immunoglobulin

A (IgA) deficiency, when the subject has antibodies against IgA
8. Subjects with a body weight of greater than 120 kg
9. Subjects with a history of anaphylaxis after previous transfusions of blood or blood products
10. Subjects for whom magnetic resonance imaging (MRI) is contraindicated or who are allergic to gadolinium
11. Pregnant or lactating women
12. Subjects who delivered a baby within 12 months before study entry (including miscarriage and stillbirth)
13. Subjects with a diagnosis of significant depression
14. Subjects with known chronic infectious diseases or malignant disease
15. Subjects with known antibody deficiencies or other autoimmune diseases other than MS
16. Subjects participating in another study during the course of this study or during the past 6 months or who have ever participated in a study investigating in new disease modifying or immunosuppressive drugs

Date of first enrolment
20/03/2009

Date of final enrolment
20/09/2010

Locations

Countries of recruitment
Austria

Germany

Study participating centre
Octapharma PPG
Vienna
Austria
1100

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