

An open-label follow-on study to assess the ongoing safety of MBP8298 in subjects with secondary progressive multiple sclerosis

Submission date 22/03/2007	Recruitment status Stopped	☐ Prospectively registered
		☐ Protocol
Registration date 18/05/2007	Overall study status Stopped	☐ Statistical analysis plan
		☐ Results
Last Edited 13/11/2013	Condition category Nervous System Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms Roxanne Morton

Contact details

6030-88 Street
Edmonton
Canada
T6E 6G4

Additional identifiers

Protocol serial number

MBP8298-SP-02

Study information

Scientific Title

Study objectives

Safety assessment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by Health Canada on 15/11/2006. Individual site approvals in Canada are ongoing, with one site currently approved and enrolling patients. Regulatory submission for the UK is pending as of 22/03/2007. All other country submissions including those for Sweden, Finland, Netherlands, Denmark, Spain, Latvia, Germany, and Estonia will occur between October 2007 and October 2008.

Primary study design

Interventional

Study design

Open-label extension study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Secondary Progressive Multiple Sclerosis

Interventions

All participants will receive 500 mg of MBP8298 intravenously once every 6 months until the termination of the study.

As of 12/08/2009 this record has been updated to include the stopped status; this trial was terminated early by the sponsor. The initial anticipated end date of this trial was 27/02/2011.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

An independent pharmacovigilance group will provide safety oversight through an ongoing and regular review of serious adverse events and aggregate laboratory alert values from all subjects to identify any potential new safety data trends. The group will confer at least quarterly with the medical monitor and will notify the sponsor within 24 hours of the observance of any potential new safety findings.

The following evaluations will be made for safety assessment each time the participant comes for an injection of study drug:

1. Evaluation of adverse events
2. Laboratory results
3. Electrocardiogram (ECG) results
4. Vital signs
5. Physical examinations

Key secondary outcome(s)

1. Expanded Disability Status Scale (EDSS) change, measured once every 6 months (prior to each dose)
2. Quality of life, measured once every 6 months (prior to each dose) by Multiple Sclerosis Quality of Life-54 (MSQoL-54). In countries where this tool has not been translated into the local language, the Short Form-36 is used.
3. Relapse rates (each confirmed relapse will be recorded)

Brain magnetic resonance imaging (MRI) scans will be carried out on an annual basis to assess the effects of MBP8298:

4. Activity analysis (T2 lesions, gadolinium enhancing lesions)
5. Lesion burden (T2 burden of disease, chronic T1 black holes)
6. Atrophy (brain)

Completion date

27/07/2009

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

1. Completion of treatment and all required evaluations of MBP8298-SP-01 (ISRCTN record of this trial at <http://www.controlled-trials.com/ISRCTN98373474>)
2. Subject must be able and willing to give meaningful, written informed consent prior to participation in the trial, in accordance with regulatory requirements
3. Subjects must be reliable, compliant, and agree to cooperate with all trial evaluations in the investigators opinion

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Pregnancy or desire to become pregnant
2. Use of any concomitant disease modifying therapy for Multiple Sclerosis (MS)

Date of first enrolment

27/02/2007

Date of final enrolment

27/07/2009

Locations

Countries of recruitment

United Kingdom

Canada

Denmark

Estonia

Finland

Germany

Latvia

Netherlands

Spain

Sweden

Study participating centre

6030-88 Street

Edmonton

Canada

T6E 6G4

Sponsor information

Organisation

BioMS Medical (Canada)

ROR

<https://ror.org/03fvjvp95>

Funder(s)

Funder type

Industry

Funder Name

BioMS Medical (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration