A multinational, multicenter, single visit, exploratory pharmacogenetic trial and long-term follow-up of the PRISMS (Prevention of Relapses and Disability by Interferon beta-1a Subcutaneously in Multiple Sclerosis) trial

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Primary objective:* To analyze the association between single nucleotide polymorphisms (SNP) markers and treatment response. Treatment response is based on the Expanded Disability Status Scale (EDSS) progression and relapse outcomes over the first 2...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system infections and inflammations
Study type	Observational invasive

Summary

ID

NL-OMON34946

Source
ToetsingOnline

Brief title
PRISMS-15

Condition

- Central nervous system infections and inflammations

Synonym
Multiple Sclerose (MS)

Research involving

Human

Sponsors and support

Primary sponsor: Merck Serono The Netherlands - a division of Merck B.V.
Source(s) of monetary or material Support: Merck Serono S.A.

Intervention

Keyword: Long-term follow-up, Pharmacogenetic

Outcome measures

Primary outcome

* Genetic markers

* BAbs/NAbs

Secondary outcome

NAP

Study description

Background summary

This is a Phase IV, interventional, multinational, multicenter, long-term follow-up, single visit, exploratory pharmacogenetic trial involving subjects who previously participated in the PRISMS trial. The PRISMS study (6789) took place 15 years ago and subsequently a follow-up study (PRISMS LTFU 22930, Long-Term Follow-Up) was performed 8 years later to assess long-term efficacy and safety.

Study objective

Primary objective:
* To analyze the association between single nucleotide polymorphisms (SNP) markers and treatment response. Treatment response is based on the Expanded Disability Status Scale (EDSS) progression and relapse outcomes over the first 2 years of treatment in the PRISMS trial.

Secondary objectives:
* To assess disease progression in subjects over the long term (14-15 years

after initial randomization).
* To assess long term immunogenicity.

Tertiary objectives:
* To analyze the association between genetic markers with responses to treatment over 2, 4, 7-8 years and 15-16 years after the initial randomization for efficacy parameters
* To analyze the association between genetic markers with responses to treatment over 2, 4, 6 and 7-8 years after initial randomization for safety parameters
* To explore the association between genetic biomarkers and other possible prognostic indicators

Study design

To address the trial objectives, a single visit will be performed. Subjects originally randomized in the PRISMS trial (560 subjects) will be recalled for this single visit, where possible. During the visit, medical and treatment history from the final visit of the PRISMS trial 6789 or the PRISMS LTFU 22930 will be retrospectively collected and a medical assessment and a blood collection for pharmacogenetics (PGx) analysis and immunogenicity assessment will be performed.

Intervention

This trial will consist of a single visit.

the following assessments will be performed:
* Medical examination:
* Multiple sclerosis (MS) history and MS treatment history review
* Neurological examination, including the EDSS score
* Blood sampling for:
* Genetic markers
* BAbs/NAbs
For safety reasons, subjects will be kept under observation for 30 minutes after blood sampling has been performed.

Study burden and risks

New scientific knowledge and technologies have become available, which were not available fifteen years ago, at the time the initial PRISMS study occured. In particular, great advances have been made in human genomics and technologies with the completion of the Human Genome Project and HapMap Project. 15 years after the initial PRISMS study, Merck-Serono has made significant progress in the understanding of the clinical and biological effects of Rebif. About 40% of subjects could potentially benefit from more efficient treatment. The present

study will help understanding the molecular basis underlying the response to Rebif while involving very minor risks or burden for the patients, who will undergo a single visit and single blood sampling without changing their current treatment.
Risks;
The needle sticks may cause local pain, bruising, swelling, lightheadedness, dizziness and rarely, fainting and/or a possible infection from the needle stick.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Randomization in the PRISMS study

Exclusion criteria

Unwilling or unable to participate in the study.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2010
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO

Date:	31-03-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01034644
CCMO	NL29867.029.10