A multinational, multicenter, single blood sampling exploratory pharmacogenetic study of the REGARD (the REbif vs Glatiramer Acetate in Relapsing MS Disease)
trial

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The overall objective of this trial is to provide additional data on the factors influencing IFN-beta response.Primary· To analyze the association between single nucleotide polymorphisms (SNP) markers and Rebif and Copaxone treatment response.…

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

Summary

ID

NL-OMON34629

Source
ToetsingOnline

Brief title
REGARD-PGx, follow-up study

Condition

- Central nervous system infections and inflammations

Synonym
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: Pharmacogenetic

Outcome measures

Primary outcome

To analyze the association between single nucleotide polymorphisms (SNP)

markers and Rebif and Copaxone treatment response.

Treatment response is based on EDSS progression and relapse outcomes over the

96 weeks of treatment in the REGARD trial.

Secondary outcome

To analyze the association between genetic markers with responses to treatment

for efficacy, safety and immunogenicity parameters.

Study description

Background summary

This is a Phase IV, interventional, multinational, multicenter, single blood sampling exploratory pharmacogenetic study involving subjects who previously participated in the REGARD trial and who did not participate in the initial PGx substudy. The estimated duration of the recruitment period is 7 months.

Study objective

The overall objective of this trial is to provide additional data on the factors influencing IFN-beta response.

Primary

· To analyze the association between single nucleotide polymorphisms (SNP) markers and Rebif and Copaxone treatment response. Treatment response is based on EDSS progression and relapse outcomes over the 96 weeks of treatment in the REGARD trial.

Secondary
· To analyze the association between genetic markers with responses to treatment for efficacy, safety and immunogenicity parameters.

Study design

This trial will consist of a single visit. Eligible subjects will be identified and invited to participate in the trial either proactively or during a routine clinic visit. If the subject consents, a single blood sample will be collected for analysis of genetic markers .
For safety reasons, subjects will be kept under observation for 30 minutes after blood sampling has been performed.

Intervention

There is only one visit with one blood drawn

Study burden and risks

During this single blood sampling, 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

Randomized patients from the REGARD 24735 study

Exclusion criteria

Patient who where already included in the initial REGARD PGx sub-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):	19-05-2010
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	17-03-2010
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	NCT01034579
CCMO	NL30060.029.09