The effect of interferon beta-1a treatment on functional adaptation in Multiple Sclerosis (MS)

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Primary: Does immunomodulation brought about by interferon beta-1a (Rebif) enhance or prolong functional reorganization in subjects with RRMS?Secondary: Does interferon beta-1a (Rebif) also affects functional connectivity as measured by resting-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON35491

Source
ToetsingOnline

Brief title
Interferon beta-1a and functional adaptation

Condition

- Autoimmune disorders
- Demyelinating disorders

Synonym
MS, multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Merck,Merck Serono The Netherlands

Intervention

Keyword: functional adaptation, interferon beta-1a, Multiple sclerosis, resting-state fMRI

Outcome measures

Primary outcome

Primary Endpoints: The mean change of each subject affected by RRMS or relapsing SPMS from baseline in functional connectivity (resting-state) fMRI at month 24.

Secondary outcome

Secondary Endpoints: Clinicial measures (progression of disability) will be measured through change in Extended Disability Status Scale (EDSS) and Multiple Sclerosis Functional Composite (MSFC). Clinical measures (progression of disease activity) as measured through the number of relapses and annualized relapse rate. Cognitive decline as measured by change in Brief Repeatable Battery * Neuropsychological tests (BRB-N) scores. Correlations fMRI and clinical/cognitive outcomes. And Requirement for treatment with corticosteroids due to relapses.

Study description

Background summary

Interferons have antiviral, anti-proliferative and immunomodulatory effects. In response to CNS (Central Nervous System) damage - including inflammation in MS - the brain has to functionally adapt. We hypothesize that the immunomodulatory effects of interferon beta-1a will amplify the effect on functional adaptation. This enhanced functional adaptation - where the function of damaged brain areas is gradually taken over by other - non-damaged * areas - will have a positive outcome on disability, progression and cognitive decline.

Study objective

Primary: Does immunomodulation brought about by interferon beta-1a (Rebif) enhance or prolong functional reorganization in subjects with RRMS?
Secondary: Does interferon beta-1a (Rebif) also affects functional connectivity as measured by resting-state functional Magnetic Resonance Imaging (fMRI) in subjects affected by relapsing SPMS? Does enhanced functional adaptation, induced by interferon beta-1a (Rebif) treatment, will reduce physical disability and cognitive decline in subjects affected by RRMS and relapsing SPMS? Does interferon beta-1a (Rebif) enhance functional brain adaptation over time, both in subjects affected by RRMS and relapsing SPMS?

Study design

The study is a prospective, single-centre, observational patient-control study assessing the effect of interferon beta-1a on functional adaptation in RRMS and relapsing SPMS patients.

Study burden and risks

All subjects need four visits at four timepoints for fMRI, BRB-N and bloodsampling. All patient subjects will also undergo neurological examination (EDSS, MSFC) at the four timepoints.

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

age 18-65
RRMS or relapsing SPMS
Meet safety criteria for MRI
Group 1: Subjects affected by RRMS starting or recently started with Interferon beta-1a treatment
Group 2: Subjects affected by relapsing SPMS on interferon beta-1a treatment.
Group 3: Untreated Subjects affected by RRMS or relapsing SPMS
Group 4: Healthy controls

Exclusion criteria

MS other than RRMS or relapsing SPMS
presence or history of psychiatric disease
presence or history of neurological disease
presence or history of alcohol or drug abuse
presence of contra-indications for MRI
presence of contra-indications for Rebif
Use of immunosupressive agents

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2011
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Rebif
Generic name:	interferon beta-1a
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	02-11-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-12-2011
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
EudraCT	EUCTR2011-003570-89-NL
CCMO	NL37559.029.11

Study results

Date completed: 05-11-2014

Actual enrolment: 22

Summary results
Trial ended prematurely