Predicting the Outcome of a Demyelinating event

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PROUD is a multicentre prospective study, using clinical factors in combination with additional tests with the aim to clarify more about the aetiology and pathogenesis of MS.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vision disorders
Study type	Observational non invasive

Summary

ID

NL-OMON43788

Source
ToetsingOnline

Brief title
PROUD Study

Condition

- Vision disorders
- Demyelinating disorders

Synonym
MS, Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: MS Research

Intervention

Keyword: Clinical Isolated Syndrom, CNS inflammation, Multiple Sclerosis, prognosis

Outcome measures

Primary outcome

Is there an association between clinical, immunological and infection

parameters and progression to MS after a first event of demyelination.

Secondary outcome

- Are current diagnostic McDonald criteria also valid for clinically isolated

syndromes in typical neurological practice (non-academic) settings?

- Are certain single nucleotide polymorphisms (SNP*s) over represented in the

subgroup progressing to clinically definite MS or associated with

benign/aggressive courses?

Study description

Background summary

Multiple Sclerosis (MS) is an autoimmune disease of the central nervous system and is a main cause of disability among young adults in the Western world. After a first clinical episode of (suspected) central nervous system demyelination, it is still hard to predict the clinical course. There has been a considerable amount of research in different fields with the aim to understand more about the cause of MS but also to predict the course of MS from the onset. Available studies have largely focussed on conventional markers, Magnetic Resonance Imaging (MRI) and cerebrospinal fluid. However, the influence of clinical parameters, such as fatigue and smoking, on developing MS after a first event has not been explored yet.

Study objective

PROUD is a multicentre prospective study, using clinical factors in combination with additional tests with the aim to clarify more about the aetiology and

pathogenesis of MS.

Study design

Patients, who fulfil the inclusion criteria, will receive by their neurologist oral and written information about the PROUD study. After the patient has decided to participate and has signed the informed consent forms, extra blood samples will be stored at the time of routine vena puncture. If a lumbar puncture is performed, extra cerebrospinal fluid will also be stored. Clinical and laboratory data will be filled on CRF's (Case Report Forms). CRF's, a copy of the MRI and the extra samples will be sent to the researchers in Erasmus MC. Also yearly policlinic visits and interim visits will be reported to the researchers in Erasmus MC.
Feces sample will be collected once. The diet questionnaire will be filled in once and send together with the faeces sample to the Erasmus MC.
Controls will be asked to hand in feces sample and fill in one questionnaire.
Patients and controls will be asked to fill in a food diary for 3 days prior to feces collection.

Study burden and risks

PROUD study is an observational study, trying to answer research questions by patient interview and clinical follow-up. Additional storage of patient samples is performed in parallel with samples for routine diagnostic purpose.
In case of fatigue two extra questionnaires (Fatigue Severity Score (FSS) and Hospital Anxiety and Depression Scale (HADS)) will be completed at the first visit and yearly control visits. The extra burden for the patient at the baseline and yearly visits will be about 6-7 minutes for FSS and HADS.
A feces sample will be collected once at baseline. Patients and controls will fill in a diet questionnaire once and a food diary for 3 days and send this together with the faeces sample to the Erasmus MC. Feces collection and the diet questionnaire together will take 10 minutes. The food diary will take 8 minutes per day (for 3 days).

Controls will hand in a feces sample once. They will fill in a diet questionnaire once and a food diary for 3 days and send this together with the faeces sample to the Erasmus MC. Feces collection and the diet questionnaire together will take 10 minutes. The food diary will take 8 minutes per day (for 3 days).

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

For patients:
1. Patients with a Clinically Isolated Syndrome (CIS) suggestive of central nervous system demyelination involving the optic nerve, brainstem or spinal cord.
2. Age > 18 years en < 50 years
3. Visit to the neurologist and clinical, blood, (CSF) and MRI examination within 6 months from the onset.;For controls for microbiome research:
1. Preferably from the same household as the patient

Exclusion criteria

For patients and controls:
Sever co-morbidity like AIDS, cancer or other severe diseases with shortening life expectance

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-11-2006
Enrollment:	1500
Type:	Actual

Ethics review

Approved WMO Date:	24-08-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-11-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL12306.078.06