Predicting the outcome of a demyelinating event

Published: 28-07-2022
Last updated: 06-04-2024

To identify prognostic factors for disease course and severity, as soluble and cellular biomarkers, immunological, genetic, radiological and demographics factors.

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

Summary

ID

NL-OMON56618

Source
ToetsingOnline

Brief title
PROUD 2.0

Condition

- Autoimmune disorders
- Demyelinating disorders

Synonym
Clinically Isolated Syndrome, Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Nationaal MS Fonds

Intervention

Keyword: Clinically Isolated Syndrome, Disease course, Multiple Sclerosis, Prognosis

Outcome measures

Primary outcome

To determine the prognostic value of various factors, such as soluble and

cellular biomarkers, immunological, genetic, radiological and environmental

factors.

Secondary outcome

N/A

Study description

Background summary

Multiple sclerosis (MS) is an autoimmune disease, characterised by inflammation, demyelination and neurodegeneration of the central nervous system (CNS). In general, the disease presents itself with a Clinically Isolated Syndrome (CIS), a first episode of suspected inflammatory demyelination. A part of the CIS-patients can be diagnosed with MS because of specific findings in the MRI of the brain or spinal cord and in the cerebrospinal fluid. With a second episode of neurological deficit based on demyelination (relapse), Clinically Definite MS (CDMS) can be diagnosed. However, a part of the patient with a CIS stay monophasic. Besides that, within de group of patient with MS great variability in disease course exists, both in frequency, location and severity of relapses and in secondary progression. In recent decades, progress has been made in the prognosis of patient after CIS in both biomarkers and in demographic and clinical factors. Despit this progress, it stays difficult to predict the outcome of patient with CIS and an (recent) diagnosis of MS. Besides that, it remains unclear why these differences in disease course and severity exist. In order to treat (with immunomodulatory treatment) and guide patient in the best possible way, it is essential to identify potential factors that (may) influence the disease course and severity.

Study objective

To identify prognostic factors for disease course and severity, as soluble and

cellular biomarkers, immunological, genetic, radiological and demographics factors.

Study design

The PROUD study 2.0 is a prospective, longitudinal observational cohort study of the course of disease after CIS in adulthood. It is a continuation of the PROUD study initiated in 2006 (MEC-2006-188). Patients who meet the inclusion criteria are approached by their neurologist. Verbal and written information about the study will be given to the potential subject. After obtaining informed consent, the standard annual check-ups as part of regular care will be expanded with additional clinical tests. During regular blood and cerebrospinal fluid (CSF) sampling additional material will be requested to be stored for the study. If no regular blood or CSF sampling is required, the patient will be asked to withdraw a sample as part of the study: this may be refused without further consequences. Data of performed MRI scans will be saved. No additional imaging is done for the study. Patients will be sent two to five digital questionnaires annually. Patients, their clinical data and the collected samples will receive a unique code under which the data will be stored. Data collection will take place by eCRF in Castor. We aim for a long follow-up of at least 5 years. At the end of the study we will re-evaluate whether an extension of the study has additional scientific value. A control group of healthy persons will also be created, in which blood will be taken once and a single digital questionnaire will be administered. There will be no follow up in the control group. The intended study is observational and designed to follow daily clinical practice. It will therefore not interfere with the standard care currently provided to CIS and MS patients. If patients participate from a recruiting centre, they may be asked to come to Erasmus MC for research up to once a year, in addition to the standard annual check-ups in their own hospital.

Study burden and risks

This is an observational study with negligible risk to the patient. For the collection of both clinical and radiological data, and for the collection of blood and CSF samples, the visits and punctures that the patient already has to undergo for regular care will be used. Questionnaires will be sent out annually and, on an optional basis, blood and liquor samples will be requested once at least five years later. These questionnaires and blood and CSF sampling are outside the scope of regular care. If patients participate from a recruiting centre, they may be asked to come to Erasmus MC, in addition to the standard annual check-ups for treatment in their own hospital, no more than once a year. There is no expected benefit for the individual patient for participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patient group:
1. Age >=18 years and <=65 years;
2. Perceived CIS: first episode of symptoms suggesting demyelination of the central nervous system
3. Inclusion is possible within 6 months of onset of symptoms.
It does not matter whether the criteria for MS diagnosis are met at inclusion.

Or: participant of original PROUD study

Control group: healthy adults, such as family members and relatives of the CIS patient at the neurology outpatient clinic.
1. Age >=18 years and <=65 years;

2. No history of chronic neurological disease or autoimmune disease

Exclusion criteria

1. Severe comorbidity with a life expectancy of 6 months or less at the time of inclusion.
2. Alternative diagnosis as infection or systemic inflammatory disease as etiology of demyelination.

Study design

Design

Study type:	Observational 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):	01-08-2022
Enrollment:	450
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	28-07-2022

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-03-2024
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	NL79673.078.21