NEURONED-MS. Multiple Sclerosis in the Netherlands. A prospective inception cohort study.

Published: 07-10-2011
Last updated: 29-04-2024

The NEURONED-MS cohort study aims to facilitate prospective observational research in the field of multiple sclerosis (MS). This cohort will serve as the central part of several projects that will be organized to address various issues including:1....

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

Summary

ID

NL-OMON41541

Source
ToetsingOnline

Brief title
NEURONED-MS. A prospective inception cohort study.

Condition

- Central nervous system infections and inflammations

Synonym
MS, multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ICF, Inception cohort, Multiple Sclerosis

Outcome measures

Primary outcome

Clinical and psychosocial data of all patients will be collected longitudinally

and prospectively on a regular basis.

Secondary outcome

not applicable

Study description

Background summary

The core objective in this project is to build up, maintain and yearly extend an inception cohort of multiple sclerosis (MS) patients in the Netherlands. This cohort is called NEURONED-MS. Most MS cohorts are recruited in tertiary centers and as such not representative for the MS population as a whole. Due to this selection bias information on physical, mental and social impact of the disease might be distorted and adequate advice to policy makers is hampered.

Study objective

The NEURONED-MS cohort study aims to facilitate prospective observational research in the field of multiple sclerosis (MS). This cohort will serve as the central part of several projects that will be organized to address various issues including:
1. the natural history of MS in the Netherlands
2. the psychosocial impact of MS on patients in the Netherlands

Study design

prospective inception cohort study

Study burden and risks

Patients will be asked yearly to complete a battery of questionnaires. The

questionnaire contains 27 pages. Administration time is approximately 30 min to 1 hour. Please see Appendix 2 in protocol for the content of the questions.
In addition, they are asked to participate in an interview by telephone, that will take approximately half an hour.

The burden can be consideren minimal. Risks are negligible.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1089a
Amsterdam 1081HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1089a
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients are eligible when they are diagnosed within the previous twelve months with MS (Polman et al., 2011), with dissemination in time and space (see protocol Appendix 3). Patients with Clinically Isolated Syndromes (CIS) may also be included if they fulfill 3 of the 4 Barkhof criteria for dissemination in space as per application of the revised McDonald criteria

(Polman et al. 2011). Patients should be 18 years or older, and live in the Netherlands, and give written informed consent.

Exclusion criteria

not able to speak dutch, refusal to give informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-03-2012
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	07-10-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-05-2015
Application type:	Amendment
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
Other	CWO-nr. 11-08
CCMO	NL36862.029.11