Project Y: searching for the cause of phenotype diversity in MS

Published: 19-06-2017
Last updated: 13-04-2024

To identify determinants that explain phenotypic variability in MS while excluding age as a confounding factor and to detect determinants which may guide intervention strategies and predict the disease course in MS.

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

Summary

ID

NL-OMON45694

Source
ToetsingOnline

Brief title
Project Y

Condition

- 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: particuliere fondsen en donaties

Intervention

Keyword: Age, Determinants, Disease course, Multiple Sclerosis

Outcome measures

Primary outcome

Clinical status (Expanded Disability Status Scale (EDSS), Multiple Sclerosis Functional Composite (MSFC)), exposure to various determinants, comorbidity, quality of life (QoL), cognitive status (neurpsychological evaluation (NPO)), imaging parameters (magnetic resonance imaging (MRI), magnetoencephalography (MEG), optical coherence tomography (OCT) and eyetracker) and Bone Mineral Density (BMD) measurement.

Secondary outcome

Not applicable.

Study description

Background summary

Detecting determinants of disease variability is pivotal to guide the search for effective therapies and optimize patient care in multiple sclerosis (MS). One of the most important confounders when studying the disease course in MS is age. We plan to recruit all people with MS born in The Netherlands in 1966, which will result in an unbiased population based cohort in which age cannot be a confounder. This cohort will be subjected to extensive examinations of a wide array of potential determinants and outcome measures.

Study objective

To identify determinants that explain phenotypic variability in MS while excluding age as a confounding factor and to detect determinants which may guide intervention strategies and predict the disease course in MS.

Study design

Population-based cross-sectional study. All participants will be asked be invited to the VUmc for a 1 day program in which all data will be collected. Total duration of the study will be 3 years.

Study burden and risks

The burden of participation consists of a 1-day visit to the VUmc (approximately 7 hours). During this day participants will undergo a series of measurements (clinical scales, NPO, MRI, MEG, OCT, eye movements) and a blood, urine and feces sample will be collected. After their visit, all participants are asked to fill in a selection of questionnaires at home (approximately 1 hour). There is no direct benefit for participants of this study.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Born in 1966 in the Netherlands
- Currently living in the Netherlands
- Diagnosis of MS

Exclusion criteria

Patients: none
Controls: comorbidity that interferes with participation in this study

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):	19-12-2017
Enrollment:	375
Type:	Actual

Ethics review

Approved WMO

Date:	19-06-2017
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
CCMO	NL61310.029.17