

# Long-term prognosis of functional outcome in Multiple Sclerosis: Changes in walking ability and the relationship with gait parameters in patients having MS for 9 years.

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Aim: 1) To continue studying (the determinants of) the decline in functioning in the domains neurological deficits, physical functioning, mental health, social functioning and general health in the first 9 years after the diagnosis, and 2) to study...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Demyelinating disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON32032

### Source

ToetsingOnline

### Brief title

Functional Prognosis in MS: changes in walking ability (FUPRO-MS III)

### 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:** St MS Research en St Nuts Ohra

## Intervention

**Keyword:** Functional prognosis, Gait, Longitudinal Cohort Study, Multiple Sclerosis

## Outcome measures

### Primary outcome

In addition to the core set of functional outcome measures and HR-QoL measures of the FuPro-study (needed to answer research question 1) instrumental measures and clinical performance tests of gait, energy consumption, muscle strength, muscle coordination, spasticity, somatosensory signs, visual symptoms, and postural stability will be performed.

### Secondary outcome

not applicable

## Study description

### Background summary

In the course of multiple sclerosis a substantial part of the patients will experience a decline in several domains of functioning. In the first 5.5 years, we observed a steady decline in mobility, which is related to impairments of the pyramidal, cerebellar and sensory tract, and energy levels.

### Study objective

Aim: 1) To continue studying (the determinants of) the decline in functioning in the domains neurological deficits, physical functioning, mental health, social functioning and general health in the first 9 years after the diagnosis, and 2) to study the relationships between neurological and physical impairments, gait characteristics, and walking ability.

Research Questions:

1. What is the longitudinal course of functioning in the domains neurological deficits, physical functioning, mental health, social functioning and general health in MS patients during the first 9 years after definite diagnosis?
2. Which gait characteristics and muscle coordination patterns are present 9 years after definite diagnosis of MS?
3. How do neurological and physical impairments (pyramidal, cerebellar and sensory tract, and energy levels) relate to these gait characteristics and muscle coordination patterns?
4. How do these gait characteristics and coordination patterns relate to the walking ability?
5. Which compensatory or adaptive strategies do (subgroups of) patients with MS use to reduce gait limitations and improve walking ability?

### **Study design**

1) Longitudinal study: extending the follow-up of an inception cohort of 156 patients with MS (FuPro-study, follow-up until 5.5 years after diagnosis) with a measurement nine years after diagnosis. 2) Cross-sectional study: in-depth analyses of neurological and physical impairments, analysis of gait characteristics, and their relationships with walking ability.

### **Study burden and risks**

Total burden of the measurements will be 6 hours (3 parts of 2 hours).  
Risks will be minimal

## **Contacts**

### **Public**

Vrije Universiteit Medisch Centrum

Postbus 7057  
1007 MB Amsterdam  
NL

### **Scientific**

Vrije Universiteit Medisch Centrum

Postbus 7057  
1007 MB Amsterdam  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Participants of the FuPRO-MS I study. Patients with recent MS were recruited in 1998-2000. This study concerns the 9-year follow-up measures of the inception cohort.

### Exclusion criteria

not applicable

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-11-2007

Enrollment: 156

Type:

Anticipated

## Ethics review

Approved WMO

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**

CCMO

**ID**

NL20264.029.07