Proxy measurements in Multiple Sclerosis

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To gain insight in the agreement and differences between patient and proxy respondents when assessing the health status of the patient en the factors that could be of influence.

Ethical review	Approved WMO
Status	Completed
Health condition type	Neuromuscular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31939

Source
ToetsingOnline

Brief title
Proxy measurements in Multiple Sclerosis

Condition

- Neuromuscular disorders

Synonym
Multiple Sclerosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Agreement, Multiple Sclerosis, Proxy, Self-report questionnaires

Outcome measures

Primary outcome

- patient-proxy agreement

- factors that can influence the patient-proxy agreement

Secondary outcome

not applicable

Study description

Background summary

There is an increasing use of self-report measurements which are based on the perspective of the patient. Reliability and validity of the outcomes can be negatively influenced when patients suffer from, for example, cognitive impairment. This could also be the case for patients who suffer from Multiple Sclerosis (MS). A possible solution for this problem might be the incorporation of a third person, a so-called proxy respondent, who can provide information on the health status of the patient that otherwise would be inaccurate or even lost. Previously performed studies on patient-proxy agreement in a small MS sample indicated that partners might be useful sources of information when assessing the physical impact of MS. However, large differences were seen on individual patient-proxy level.

Study objective

To gain insight in the agreement and differences between patient and proxy respondents when assessing the health status of the patient en the factors that could be of influence.

Study design

This is a prospective cohort study, which will be performed at the outpatient clinic of Neurology of the VU Medical Center, Amsterdam. MS patients and their partners will be asked to participate. Assessments will be scheduled according to visits that were already planned to limit possible burden. During the assessments both patients and their partners will complete several questionnaires, independently from each other. These assessments will be repeated six months and two years after baseline. At baseline, the patients

will also undergo different tests including a neurological examination, functional tests and a neuropsychological test battery.

Study burden and risks

MS patients and their partners will have to complete several questionnaires. Their will be a short-term follow-up at six months and a long-term follow-up after two years. Assessments will be linked to already planned visits. Patients will also undergo neurological scoring, tests to assess neurological functioning and a neuropsychological test battery. To our opinion, the advantages of possible results outweigh the limited burden that could be introduced when participating in this study.

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

Inclusion criteria patients:
1. Adult (>18 years)
2. Multiple Sclerosis according to McDonald criteria
3. Signed informed consent;Inclusion criteria proxy respondents:
1. Adult (>18 years)
2. Partner of the patient
3. Signed informed consent

Exclusion criteria

Exclusion criteria patients:
1. Severe cognitive impairment which makes it impossible to complete a questionnaire.
2. When the patient does not have a partner;Exclusion criteria proxy respondents:
1. When the proxy respondent is not the partner of the patient

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	30-12-2008
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	23-12-2008
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	NL23779.029.08