Assessment of the link between subjective complaints and objective impairment in motor and cognitive functioning after stroke

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Structural brain disorders
Study type	Observational non invasive

Summary

ID

NL-OMON50406

Source
ToetsingOnline

Brief title
Motor and cognitive impairment in stroke

Condition

- Structural brain disorders

Synonym
cerebro vasculair accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,de instelling waar een van de hoofdonderzoekerswerkzaam is en het onderzoek wordt uitgevoerd;Maxima Medisch Centrum

Intervention

Keyword: cognitive, impairment, motor, stroke

Outcome measures

Primary outcome

Primary parameters are motor and cognitive impairment after stroke

Secondary outcome

The link between motor and cognitive impairment

Study description

Background summary

The prevalence of both motor and cognitive impairment after stroke is high and persistent. Focus of attention in both patients, proxies and professionals in the first weeks to months after stroke is usually on visible motor impairment, like paresis. The often invisible cognitive impairment might stay underexposed for a considerable amount of time. Nevertheless, cognitive impairment affects both rehabilitation success and quality of life of both patient and their carers. More information is needed about possible links between specific motor and cognitive impairment after stroke as well as about the possibility to use motor impairment to predict cognitive impairment.

Study objective

The general objective of this study is to gain more understanding of motor and cognitive impairment and the way these two are linked after stroke. There are two more specific objectives: exploring (1) the link between motor and cognitive impairment after stroke and (2) the possibility to use motor impairment to predict cognitive impairment in the first two years after stroke.

Study design

By means of a prospective follow-up study, stroke patients will be assessed with both motor and cognitive instruments on three separate occasions: at

three, twelve and twenty-four months after stroke. Both objective tasks and more subjective ratings scales and questionnaires will be used.

Study burden and risks

During this study there will be three assessments, each taking approximately two hours and consisting of an interview and a neuropsychologisch assessment in the hospital setting. The total burden for participants is estimated to be six hours in a period of two years, divided in three assessments each lasting for two hours. The study is non-invasive, there are no specific risks and participants will be compensated for traveling expenses. With the results of this study we aim to gain more understanding of motor and cognitive impairment after stroke and the way these two are linked. The overall aim of the study is to improve the future care for stroke patients and therefore health benefits for participants are not expected. In case of individual results that give rise to concern, participants will be referred to their physician. Due to the clinical and social importance of the aims of this study and the fact that participating does not result in specific risks, the burden for the participants seems justifiable.

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

Clinical diagnosis of stroke (first or recurrent), ischaemic or intracerebral haemorrhagic.
Age > 18.
Sufficient understanding of Dutch language.

Exclusion criteria

Clinical diagnosis of Transcient Ischemic Attack (TIA) or Subarachnoidal bleeding (SAB).
Premorbid cognitive decline as defined by a IQcode score > 3.6.
Premorbid severe psychiatric or neurological problems, for example a delirium
Communication problems which make neuropsychological examination and/or the use of questionnaires impossible (e.g. blindness, deafness, severe aphasia).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-02-2017
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	07-06-2016
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	21-07-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL56866.015.16