Fatigue and Cognitive Disorders after Minor Stroke

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Primary: to study the frequency and characteristics of fatigue and cognitive disorders after minor stroke. Secondary: to gain more insight in the aetiology of post-stroke fatigue and evaluate the impact of post-stroke fatigue on personal and social...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON37720

Source
ToetsingOnline

Brief title
FAMS

Condition

- Central nervous system vascular disorders
- Cognitive and attention disorders and disturbances

Synonym
Cerebrovascular accident, stroke

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cognition Fatigue Stroke

Outcome measures

Primary outcome

- Prevalence of post-stroke fatigue at 3 months and 1 year after a minor stroke, defined as an FSS (Fatigue Severity Scale) score >= 4 in combination with a validated case definition for post-stroke fatigue (*Over the past month, there has been at least a 2-week period when patient has experienced fatigue, a lack of energy, or an increased need to rest every day or nearly every day. This fatigue has led to difficulty taking part in everyday activities*)

- Characteristics of post-stroke fatigue as assessed by the MFI-20 (Multidimensional Fatigue Inventory) and a semistructured interview

- Prevalence of cognitive disorders at 4 months after stroke, with cognitive disorders defined as a score < 25th percentile on >= 2 cognitive subdomains AND/OR a score < 5th percentile on 1 cognitive subdomain (as compared to norm groups)

- Characteristics of cognitive disorders: description of the neuropsychological profile of minor stroke patients with cognitive deficits

Secondary outcome

- Correlations of anxiety and depression, coping, sleep disturbances, pro- and anti-inflammatory markers, stroke characteristics and cognitive dysfunction with fatigue

- Correlations of quality of life, return to work and activity level with

fatigue

Study description

Background summary

Post-stroke fatigue and cognitive disorders frequently occur in a general stroke population. A formal evaluation in a minor stroke population is lacking, but even in the absence of major neurological deficits, fatigue and cognitive disorders may have a major impact on quality of life after stroke. However, the underlying mechanisms are poorly understood. A number of pathogenic correlates have previously been proposed (such as depression, coping, sleeping disorders, inflammation, stroke characteristics, and neuroendocrine dysregulation). However, these different systems have never been studied in parallel and their differential contributions to fatigue and cognitive disorders after a minor stroke are unknown.

Study objective

Primary: to study the frequency and characteristics of fatigue and cognitive disorders after minor stroke.
Secondary: to gain more insight in the aetiology of post-stroke fatigue and evaluate the impact of post-stroke fatigue on personal and social outcome.

Study design

Prospective observational study (longitudinal design).

Study burden and risks

No risk is related to participation in this study. The extensive characterisation of fatigue and cognitive disorders after stroke as well as the focus on explanatory variables through history taking, physical examination, questionnaires, laboratory investigation and imaging, may pose a burden on the patient, but has the goal to better understand and potentially alleviate the disease burden of stroke.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

a. Clinical first-ever minor ischemic stroke (with minor defined as National Institutes of Health Stroke Scale [NIHSS] score <= 5 within 24 hours after onset)
b. Age 18 years or older
c. Previously independent for their daily living activities
d. Exhibiting sufficient cognitive functioning to participate (score on the mini-mental state examination (MMSE) >20)

Exclusion criteria

a. Not having enough understanding of the Dutch language
b. Not being able to attend follow-up visits due to home address outside catchment area of UMCG
c. Prior disability (modified Rankin Scale [mRS] > 1)
d. Presence of one or more of the following in the 15 days prior to inclusion: chronic inflammatory diseases, severe hepatic or renal diseases, haematological diseases, cancer, infectious disease, anti-inflammatory or immune suppressing therapy
e. Pre-existent neurological or psychiatric illnesses (as described in the patient*s medical file)

f. No informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-09-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL38873.042.12