

Fatigue in CVA patients: an underexposed issue

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular haemorrhagic disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32172

Source

ToetsingOnline

Brief title

FATSTROKE

Condition

- Vascular haemorrhagic disorders

Synonym

cerebral vascular accident, stroke

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cerebral vascular accident, Fatigue

Outcome measures

Primary outcome

Level of quality of life at follow-up, adverse events and death at follow-up.

Secondary outcome

nvt

Study description

Background summary

Symptoms of fatigue after a stroke is a neglected issue. Little is known about the determinants of fatigue and the prognostic value of fatigue in stroke patients. Since patients often rate fatigue as one of their worst symptoms affecting their quality of life, it is important to gain knowledge about its predictors and to examine its predictive value.

Study objective

The objective of the current study is to determine whether cognitive, emotional, behavioural, and personality explain individual difference in fatigue symptomatology. Furthermore, this study wants to examine whether fatigue is a risk marker for adverse prognosis in stroke patients.

Study design

Above objectives will be investigated using a longitudinal study design.

Study burden and risks

There is no additional risk associated with participation. Patients are asked to participate in a neuropsychological examination at baseline and 3-month follow-up, and fill out a questionnaire booklet at baseline, 3-month follow-up, and 12-month follow-up. Patients are asked to participate 3 times.

Contacts

Public

Universiteit van Tilburg

Warandelaan 2
5000LE Tilburg
Nederland

Scientific

Universiteit van Tilburg

Warandelaan 2
5000LE Tilburg
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

CVA

Discharged from Neurology ward

Exclusion criteria

Patients with impaired level of consciousness, with severe problems in language comprehension, multiple cognitive impairments reflecting dementia syndrome, as well as patients who were in peril of death are excluded.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 19-03-2008

Enrollment: 300

Type: Actual

Medical products/devices used

Registration: No

Ethics review

Approved WMO

Date: 10-03-2008

Application type: First submission

Review commission: METC Brabant (Tilburg)

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	NL21642.008.08