Predictors of quality of life one year after stroke or TIA

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The first aim of this study is to determine the QoL of patients one year post-stroke. The second aim of this study is to define the predictors of the QoL one year post-stroke

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON43276

Source
ToetsingOnline

Brief title
QoL after stroke/TIA

Condition

- Other condition

Synonym
stroke

Health condition

beroerte of TIA

Research involving
Human

Sponsors and support

Primary sponsor: OLVG Oost
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: predictors, quality of life, stroke, TIA

Outcome measures

Primary outcome

Quality of life one year after stroke will be established by means of the total

RAND-36 score. Furtermore, it will be checked if the improvement or

deterioration of the quality of life can be declared on the basis of the

Hospital Anxiety and Depression Scale and mRS score, which have been determined

one year post-stroke or TIA by using a multiple lineair regression analysis

($\alpha=0.05$). Finally, the predictors of quality of life one year post-stroke will

be determined by also using a multiple lineair regression analysis ($\alpha=0.05$).

Secondary outcome

N/A

Study description

Background summary

In the Onze Lieve Vrouwe Gasthuis (OLVG) approximately 500 patients visited the hospital or were hospitalized between April 2013 and February 2016 due to a cerebrovascular accident (CVA). When the symptoms (loss of body functions) disappear within 24 hours or within a few days, the patient suffered a TIA or a minor stroke. After a while, however, most patients experience or develop physical limitations, and cognitive or emotional impairments. This is the reason why the OLVG arrange in collaboration with the Beroerte Advies Centrum (BAC) [translation: Stroke Advice Centre] a follow-up meeting. It is important to determine the quality of life of patients who suffered a stroke one year ago, because quality of life is an important aspect of life after suffering a stroke. More insight into the quality of patients one year post-stroke can help to optimise life following stroke. It is also important to define the predictors of quality of life one year post-stroke, because rehabilitation can focus on these predictors resulting into an improved QoL of patients after

stroke.

Study objective

The first aim of this study is to determine the QoL of patients one year post-stroke. The second aim of this study is to define the predictors of the QoL one year post-stroke

Study design

Patients will be asked to fill out 4 questionnaires:
1. RAND-36
2. Hospital Anxiety and Depression Scale (HADS) with a few disease-specific questions added to the questionnaire.
3. Patient Reported Outcome Measurement Information System-10 (PROMIS-10)
4. Additional information questionnaire
Besides, a certified researcher will determine the modified Rankin Scale score of the patients.

Study burden and risks

The burden and risks associated with participation are very slight. The patient will spent in total 55 minutes to complete the questionnaires and to determine the modified Rankin Scale score.

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

Patients who suffered a stroke or TIA one year ago (±2 months), came to the follow-up hospital visit arranged by the Onze Lieve Vrouwe Gasthuis and Beroerte Advies Centrum, completed the Hospital Anxiety and Depression Scale and/or RAND-36 and of whom a modified Rrankin Scale score is determined.

Exclusion criteria

Patients younger than 18 years old, with severe residual symptoms, with dementia, severe behavioral impairments and do not understand the Dutch language.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2016
Enrollment:	130

Type:	Actual

Ethics review

Approved WMO Date:	21-07-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL57074.100.16