

Validation of the modified Hetero Anamnestic screening instrument for Cognition (HAC-modified): a prognostic instrument in determining outcome after stroke.

Published: 28-06-2013

Last updated: 25-04-2024

Validation of the modified Hetero Anamnestic screening instrument for Cognition (HAC-modified): a prognostic instrument in determining outcome after stroke.

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38978

Source

ToetsingOnline

Brief title

Validation of HAC-modified in stroke patients.

Condition

- Central nervous system vascular disorders

Synonym

Cerebrovascular Accident, Stroke

Research involving

Human

Sponsors and support

Primary sponsor: RMC Groot Klimmendaal Arnhem

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

Intervention

Keyword: Cognition, Prognosis, Stroke, Validation

Outcome measures

Primary outcome

Spouses/close relatives: HAC-modified (10-15 minutes)

Patients: cognitive examination (90 minutes)

- MMSE: orientation, serial seven
- ADS-8 wordtest
- Keyfindingtest
- Complex figure of Rey (part drawing)
- Stroop
- WAIS, similarities
- FAST (Frenchay Aphasia Screening Test), (language comprehension, expression)
- Digit symbol substitution test

Secondary outcome

Not applicable

Study description

Background summary

No validated instrument exists which assesses pre-stroke cognitive functioning. Knowledge of pre-stroke cognitive problems is of importance, since the presence of pre-stroke cognitive problems can influence post-stroke outcome. This

knowledge is also important for setting achievable rehabilitation goals. Hence we created the modified Hetero Anamnestic screening instrument for Cognition (HAC-modified), which is an improved version of the HAC, which is more simplified and not validated. The HAC-modified is an instrument assessing pre-stroke cognitive functioning through questioning spouses or close relatives on possible problems on everyday activities of the stroke-patient. Validation of the HAC-modified is mandatory to assess reliability in clinical practice.

Study objective

Validation of the modified Hetero Anamnestic screening instrument for Cognition (HAC-modified): a prognostic instrument in determining outcome after stroke.

Study design

Observational study

Study burden and risks

The burden for stroke patient and spouses/close relatives is low; testing takes place only once and will take 90 minutes for stroke patients and 10-15 minutes for spouses/close relatives.

There are no risks associated with participation, benefit and group relatedness, since it is a onetime assessment of cognitive functioning during which no invasive procedures take place and no therapeutic effect is intended.

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:

- Age 18-80 years
- Diagnosed with stroke (hemorrhagic or ischemic)
- Stable neurological situation, at least 3 months post-stroke
- No, minor or severe cognitive problems

Healthy subjects

- Age 18-80 years
- No cognitive problems (younger population) or some cognitive problems (elderly population)

Exclusion criteria

Patient

- Severe communication problems
- Mental retardation
- Other disease (except stroke) possibly affecting cognitive functioning (neurologic, psychiatric or internal disease)
- Neuropsychological testing less than 3 months ago

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2013
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO	
Date:	28-06-2013
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL43934.072.13