

Long term consequences of subarachnoid hemorrhage;;Long-term effects on quality of life after a subarchnoid hemorrhage: the influence of cognition

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The primary research question is:-What is the influence of cognitive functioning on on the quality of life after SAH on the long term?Two secondary research questions are:-Is there a specific neuropsychological profile after SAH on the long term?-...

Ethical review	Approved WMO
Status	Suspended
Health condition type	Aneurysms and artery dissections
Study type	Observational non invasive

Summary

ID

NL-OMON30938

Source

ToetsingOnline

Brief title

SAB-cog

Condition

- Aneurysms and artery dissections

Synonym

hemorrhage, stroke

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

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

Intervention

Keyword: cognition, neuropsychology, quality of life, subarchnoid hemorrhage

Outcome measures

Primary outcome

Primary outcome measure: Quality of life

The main purpose of this present study is to assess the relation between cognitive functioning and quality of life. To assess the multi-dimensional character of quality of life we used two different measures, the first measure is an illness-specific questionnaire, namely the Stroke-Specific Quality of Life (SS-QOL). The second measure is a generic measure for subjective well-being, the Life Satisfaction 9 (LiSat9), which contains 1 question about general satisfaction about life and eight questions about satisfaction of specific domains. Both measures will be used as outcome measures

Secondary outcome

Cognitive functioning:

With testresearch we will explore the cognitive functioning of the SAB-patient on the most important cognitive domains, namely general functioning, language, verbal memory, non-verbal memory, executive functioning and visuo-perception and construction. Each domain will be represented by a domainscore. Besides that an overall score of cognitive functioning will be created for each patient.

Cognitive complaints:

This information is gathered by means of the Cognitive Failure Questionnaire (CFQ). This questionnaire measures in which amount somebody experiences cognitive mistakes (like forgetting things).

Study description

Background summary

Clinical experience and other studies showed that patients with Subarachnoid Hemorrhage often experience cognitive and psychological problems despite a good physical and neurological recovery on the long term. These problems seem to effect the so called quality of life.

Most studies focused on cognitive and psychological functioning shortly after SAH. This study shall focus on cognitive functioning and its influence on quality of life 1,5 to 4 years after SAH. A better understanding of the cognitive problems is desirable for arranging the best care with the best possible result for patient as his environment. This study is built up of 2 different parts. One part consists of different questionnaires. METC Utrecht decided that the study doesn't fall within the scope of the Law of Medical Research (WMO).

The neuropsychological examination consists of a semi-structured interview for examining cognitive complaints and different validated neuropsychological tests selected on the basis that they tapped functions that have been found in other studies to be most sensitive to subtle cognitive impairments in patients with SAH.

Study objective

The primary research question is:

-What is the influence of cognitive functioning on the quality of life after SAH on the long term?

Two secondary research questions are:

-Is there a specific neuropsychological profile after SAH on the long term?

-What is the relation between cognitive complaints and cognitive functioning?

Study design

This research is a cross-sectional study.

Study burden and risks

There will be no risks.

The semi-structured interview will take 10 minutes. After this the testresearch will be presented which consists of validated neuropsychological material and wich will take about 75 minutes. The research will take place at the polyclinic in UMC Utrecht. For the trip to Utrecht the patient will receive travellingcost. When it*s impossible for the patient to visit the polyclinic the researchers will make an appointment for a housevisit.

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

-All patients who were admitted and treated for an Subarchnoid hemorrhage caused by an aneurysm at UMC Utrecht and who are registered in the SAB database

of Trialbureau Neurology of UMC Utrecht and who gave written permission to be invited for neuropsychological examination.
gave written

Exclusion criteria

- primary infarct or hemorrhage
- not enough knowledge of the Dutch language
- other invalid permorbid impairments with consequences for the Daily Life (ADL) or of influence on cognition
- an age outside the range of age 20 to 80.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Suspended

Start date (anticipated): 01-03-2007

Enrollment: 80

Type: Anticipated

Ethics review

Approved WMO

Date: 18-12-2007

Application type: First submission

Review commission: METC NedMec

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	NL16422.041.07