Subarachnoid haemorrhage (SAH): brain damage, cognitive and behavioral functioning as predictors of recovery.

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

Summary

ID

NL-OMON54915

Source
ToetsingOnline

Brief title
Subarachnoid haemorrhage (SAH): brain injury, cognition and behaviour.

Condition

- Aneurysms and artery dissections

Synonym
intracranial haemorrhage, subarachnoid haemorrhage

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: subsidie van stichting Catharina Heerdt

Intervention

Keyword: brain damage, cognitive functioning, neuro-imaging, subarachnoid haemorrhage

Outcome measures

Primary outcome

The primary outcome measure consists of the score on the Impact on

Participation and Autonomy (IPA) (Cardol, 2005) questionnaire 1 year after SAH.

Secondary outcome

- The score on the IPA 2 years after SAH;

- The score on the mRS 1 and 2 years after SAH;

- Performance on neuropsychological tests (intelligence, memory, attention,

mental speed, language, visuoconstruction skills, executive functions and

social cognition);

- Scores on questionnaires (complaints, fatigue, anxiety/depression, stress,

coping, personality, behavior, quality of life)

- Neuro-imaging outcomes (RS-fMRI, DWI, VBM)

o ASL/VAI: cerebral blood flow (CBF), cerebral blood volume (CBV), vessel size,

oxygen saturation, vessel architecture

o DTI: fractional anisotropy (FA) en apparent diffusion coefficient (ADC)

o SWI/QSM: affected tissue volume en hemosiderosis volume

o Synthetic MRI: quantitative T1, T2, proton density (PD) values.

Study description

Background summary

A subarachnoid haemorrhage (SAH) is a serious condition with a high mortality (30%). After a SAH, diffuse injury occurs, not only due to the initial bleeding, but also due to complications (vascular spasms, hydrocephalus, renewed bleeding) and secondary damage. For this reason, there is no clear relationship between brain damage and outcome after a SAH. Those who survive a SAH have a high risk of complications and negative long-term effects. Previous studies have shown that more than 50% of all patients are unable to resume previous work even in the absence of physical limitations (Al-Khindi, Macdonald, & Schweizer, 2010; Passier, Visser-Meily, Rinkel, Lindeman, & Post, 2011). In addition, patients experiences problems in carrying out leisure activities and social contacts after a SAH (Buunk, Groen, Veenstra, & Spikman, 2015).

Cognitive, emotional and behavioral consequences may occur after a SAH. For example, after a SAH both disorders in basic cognitive functions (memory, attention, pace and language) and so-called 'higher order' functions (executive functions, social cognition) are found (Al-Khindi et al., 2010; Buunk et al. al., 2016; Rinkel & Algra, 2011). Other possible residual symptoms of a SAH are subjective complaints such as fatigue and anxiety and mood complaints. In addition, changes in behavior and personality are found regularly (Buchanan, Elias, & Goplen, 2000; Ogden, Utley, & Mee, 1997; Storey, 1972).

In the existing literature, little is known about the early predictors of long-term recovery after SAH. In this context, recovery is understood as functioning at the participation level, with emphasis on both resuming and maintaining work and social life in the long term. The focus of the current study is on increasing this knowledge by following 150 SAB patients for two years. A neuropsychological examination and MRI scan are performed 6 months after the SAH (standard clinical care). In addition, 6 months, 1 year and 2 years after SAB questionnaires will be sent to map, among other things, emotional and behavioral changes, fatigue, quality of life and resumption of work and social activities (in the context of research).

In previous studies, imaging techniques such as Magnetic Resonance Imaging (MRI), have been used to better understand the outcomes of a SAH and to ultimately predict them. However, the use of these methods in predicting outcomes after a SAH remains experimental (de Oliveira Manoel et al., 2014) and in particular the consequences of white matter lesions are unknown. We believe there are some promising imaging techniques, which are not or barely used, that can help in research on the (cognitive) effect of SAH and the predictive value of long-term outcome. First, Diffusion Tensor Imaging (DTI) can map the relationship between (damage to) white matter pathways and cognitive and behavioral complaints. Only few studies used DTI to study brain damage after SAH (Chaudhary et al., 2015; Sener et al., 2016; Yeo et al., 2012). The relation between outcome (daily functioning, complaints, cognitive functions) and DTI has not yet been studied. There are some MRI techniques that have not yet been used in SAH patients: Arterial Spin Labeling (ASL), Quantitative

Susceptibility Mapping (QSM), Vessel Architectural Imaging (VAI) and Synthetic MRI. ASL and QSM data can be used to measure respectively the blood transduction of brain tissue (perfusion) and the quantitative damage of blood products outside the vessels. In addition, VAI is a new Dynamic Susceptibility Contrast (DSC) perfusion sequence that can demonstrate microvascular architecture and oxygen saturation status. Finally, synthetic MRI is a technique whereby a single scan can create multiple different contrast weighted snapshots and can quantify myelin and damage. In short, the application of new techniques can perform important new insights into cognitive impairment and limited mode after an SAB.

Study objective

The research project focuses on identifying early predictors (brain damage, cognition and behavior) for recovery after a SAH. The research also focuses on using advanced neuro-imaging for better mapping of (indicators of) brain damage after a SAH, which will also be included as predictors. In this context, recovery is understood as functioning at the participation level, emphasizing both resuming and maintaining work and social life in the long term.

Study design

This is a longitudinal study in which patients are followed for two years.

Study burden and risks

The neuropsychological assessment, the MRI scan and questionnaires can be exhausting for patients. Both the neuropsychological assessment and the MRI scan are part of standard clinical care, but additional sequences will be added to the MRI scan. Because of the VAI, patients will receive contrast for this MRI. They will undergo a venipuncture in the elbow. This has very limited risk, however, in exceptional cases a local bleeding may occur. There is also the risk of an allergic reaction to the contrast medium used in our study (Dotarem), although this is extremely rare. Patients will be informed about adding additional MRI sequences and the total MRI scan will take approximately one hour. The neuropsychological assessment takes a maximum of three hours, during which time patients can take a break. 6 months, 1 year and 2 years after SAB, questionnaires will be sent, which patients can complete at home.

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

1. A SAH patient, the diagnosis being based on clinical features in combination
with CT angiography (CTA) or digital subtraction angiography (DSA).
2. The patient must be able to understand the instructions of the
neuropsychological assessment and be mentally and physically able to undergo
the research activities; this will be assessed in a consultation between the
treating doctor (neurosurgeon) and researcher (neuropsychologist).
3. Sufficient knowledge of the Dutch language.
4. Age 18 or older

Exclusion criteria

A limited physical and/or cognitive condition which makes it impossible for
patients to undergo the neuropsychological assessment and MRI.

Study design

Design

Study type: Observational invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 18-11-2019

Enrollment: 235

Type: Actual

Ethics review

Approved WMO
Date: 22-08-2019

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO
Date: 26-11-2019

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO
Date: 29-03-2021

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO
Date: 08-06-2021

Application type: Amendment

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	NL69873.042.19