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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22031

Bron
Nationaal Trial Register

Verkorte titel
ICONS

Aandoening

Subarachnoid haemorrhage

Ondersteuning

Primaire sponsor: Catharina Heerdt foundation
Overige ondersteuning: Catharina Heerdt foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure consists of the score on the Impact on Participation and Autonomy (IPA) (Cardol, 2005) questionnaire 1 year after SAH.

Toelichting onderzoek

Achtergrond van het onderzoek

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 3 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.

Doel van het onderzoek

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.

Onderzoeksopzet

6 months after SAH: neuropsychological assessment (including outcome measures), MRI and questionnaires
1 year after SAH: outcome measures and questionnaires
2 years after SAH: outcome measures and questionnaires

Contactpersonen

Publiek

University Medical Center Groningen
LS Jorna

0652129401

Wetenschappelijk

University Medical Center Groningen
LS Jorna

0652129401

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2019
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-06-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7803
Ander register	METc UMC Groningen : 201900273

Resultaten