COACH-pilot study; COgnition After intraCerebral Hemorrhage

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23317

Source
NTR

Brief title
COACH-pilot

Health condition

Intracerebral hemorrhage and dementia

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: This research has been made possible by the Dutch Heart Foundation and the Netherlands Organisation for Scientific Research (NWO), as part of their joint strategic research programme: Earlier recognition of cardiovascular diseases. This project is partially financed by the PPP Allowance made available by Top Sector Life Sciences and Health to the Dutch Heart foundation to stimulate public-private partnerships

Intervention

Outcome measures

Primary outcome

The main parameters are cognitive decline (according to the neuropsychological assessment) at 12 months.

Secondary outcome

Secondary outcomes are burden of SVD markers on MRI and CSF markers at baseline, at six months and 12 months.

Study description

Background summary

Dementia is a major contributor of dependence and disability in the ageing population and is mainly caused by neurodegenerative and cerebrovascular disease. Vascular cognitive impairment (VCI) occurs in at least 10% of patients who recover from an intracerebral hemorrhage (ICH) and has a major impact on post ICH recovery. In the acute phase of ICH, cognitive impairment may be caused directly by the hemorrhage damaging the brain parenchyma. In the chronic phase, however, further cognitive decline is also prevalent. Cognitive decline after ICH might be caused by the underlying etiology of the ICH. The most frequent underlying small vessel diseases (SVD) that cause ICH are cerebral amyloid angiopathy (CAA) and hypertensive arteriopathy (HA). CAA and HA have their own radiological signatures of SVD markers which allow for in vivo tracking of disease progression using MRI. Although the initial clinical presentation these two types of SVD differs – CAA classically presents with a lobar ICH, whereas HA causes deep ICH – both groups of patients are at risk of developing dementia. However, it has recently been shown that patients with lobar ICH develop new onset dementia twice as often as patients with deep ICH. Whether underlying CAA pathology causes this increase, remains unclear. In addition, whether ICH accelerates the process of vascular damage and if cognitive decline can be predicted by certain disease markers is uncertain. Understanding the underlying mechanisms for cognitive decline after ICH helps to improve knowledge of prognosis and clinical management of patients who are recovering from ICH.

Objectives: The overall aim of this pilot study is to investigate the development of MRI and CSF markers after CAA-related and HA-related ICH in relation to cognitive decline. The results from this pilot trial will be used to design a larger cohort study to investigate underlying mechanisms of cognitive decline after ICH.

Methods: Data will be collected at four measuring points: at baseline (during hospital admission for the ICH or at the outpatients clinic within one month of presentation with an acute ICH), after three months, after six months and after 12 months. Premorbid cognitive functioning will be assessed with the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) to select participants without pre-existing cognitive impairment. At baseline, the premorbid functional status will be assessed with the modified Rankin Scale (mRS) and Barthell index. A 3Tesla MRI will be performed to assess the most likely underlying

cause of the ICH (patients with either CAA or HA-related ICH will be included). Stroke severity will be assessed with the National Institutes of Health Stroke Scale (NIHSS) and a neurologic exam will be performed. Participants will undergo an extensive interview on life-style, vascular risk factors and medication, and will undergo a blood withdrawal. Neuropsychological testing will be performed and questionnaires will be used for screening for depression, anxiety and psychopathology. In addition, participants will be asked to undergo a lumbar puncture to collect cerebrospinal fluid (CSF).
After three months, neurological examination, and neuropsychological testing will be repeated.
After six and 12 moths, the neurological examination, the 3 Tesla MRI and neuropsychological testing will be repeated. Additionally, participants will be asked for a lumbar puncture at these two time points.
Main study parameters/endpoints: The main parameters are cognitive decline (according to the neuropsychological assessment) at 12 months. Secondary outcomes are burden of SVD markers on MRI and CSF markers at baseline, at six months and 12 months.

Study design: The study design is a prospective cohort study.

Study objective

Cerebral amyloid angiopathy is an important predictor for cognitive decline after intracerebral hemorrhage

Study design

12 months

Intervention

N.A.

Contacts

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Eligibility criteria

Inclusion criteria

ICH patients:
1. Age ≥ 55y 2. Ability and willingness to provide written informed consent. 3. Supratentorial ICH with CAAa or HAb as the most likely cause.
a CAA-related ICH is defined as an ICH that meets the criteria for definite or probable CAA according to the Modified Boston Criteria (appendix A) b HA-related ICH is defined as ICH located in the basal ganglia, thalamus, or the deep white matter and the presence of hypertension defined as: on treatment for hypertension, or known with high blood pressure (two measurements SBP >140 or DBP >90 mmHg) but not treated for hypertension.

Exclusion criteria

5.3 Exclusion criteria
1. Age < 55y
2. Unable to provide informed consent.
3. Pre-existing cognitive impairment assessed with the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE); scores between 53 - 63 reflect pre-existing cognitive mpairment.
4. Contra indications, such as: Contra-indications for 3T MRI and contraindications for lumbar puncture:

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	19-08-2021
Enrollment:	32
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date:	19-08-2021
Application type:	First submission

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
NTR-new	NL9686
Other	METC LDD : P20.109

Study results