COACH-pilot study, COgnition After intraCerebral Hemorrhage Assessing cognitive function and related small vessel disease markers after intracerebral hemorrhage; a pilot study.

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

Summary

ID

NL-OMON52189

Source
ToetsingOnline

Brief title
COACH-pilot study: COgnition After intraCerebral Hemorrhage

Condition

- Central nervous system vascular disorders

Synonym
brain hemorrhage

Research involving
Human

Sponsors and support

Primary sponsor: Neurologie
Source(s) of monetary or material Support: Brain@Risk

Intervention

Keyword: dementia, intracerebral hemorrhage, mild cognitive impairment, stroke

Outcome measures

Primary outcome

The main parameters are cognitive decline (according to the Mini Mental State Examination [MMSE]) at 12 months.

Secondary outcome

Other study parameters are date of birth, sex, medical history, alcohol/drug/caffeine consumption, smoking, medication, cardiovascular risk factors, neurological history, BMI, blood pressure and APOE genotype. Blood and CSF markers will also be analysed, as well as SVD markers on the baseline MRI.

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. Dementia 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.

Study objective

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.

Study design

The study design is a prospective cohort study.

Study burden and risks

The risks of MRI are minimal (risk of everyday life), because there are no consequences to the health of the participant. Contra-indications will be carefully investigated per subject, burden will be kept at a minimum by using short protocols. There is no direct benefit for the patients except for more insight into the underlying pathophysiology of the hemorrhages related to their disease.
Blood withdrawal and lumbar puncture are routine procedures at the Department of Neurology. Lumbar puncture will be performed by experienced physicians. We will use atraumatic spinal needles to reduce the risk of post-lumbar puncture headache.
Patients will be informed extensively about the potential risks of these procedures, after which written informed consent will be obtained.

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. Age >= 55years
2. Ability and willingness to provide written informed consent.
3. Supratentorial ICH with cerebral amyloid angiopathy or hypertension related arteriopathy as the most likely cause.

Exclusion criteria

1. Age < 55y
2. Unable to provide informed consent.
3. Pre-existing cognitive impairment
4. Contra-indications for 3Tesla MRI.
5. Contraindications for lumbar puncture

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-04-2022
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	15-06-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	01-10-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	27-09-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL74864.058.20