The Follow-up in sporadic Cerebral Amyloid Angiopathy Study

Published: 07-02-2018
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The overall aim of this study is to investigate clinical risk factors and MR markers that affect disease progression to gain more insight in targets for prevention and therapy and to better inform patients on prognosis.

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

Summary

ID

NL-OMON52554

Source
ToetsingOnline

Brief title
FOCAS

Condition

- Central nervous system vascular disorders

Synonym
CAA, sCAA, sporadic cerebral amyloid angiopathy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CAA, cerebral amyloid angiopathy, disease course, sporadic

Outcome measures

Primary outcome

The main parameters are microvascular CAA markers on 3T-MRI and 7T-MRI, changes in CSF, recurrence ICH rate and clinical outcome.

Secondary outcome

Other studyparameters will include: date of birth, gender, medical history, consumption of alcohol/caffeïne/drugs, smoking, medication use, cardiovascular risk factors, neurological history, BMI, blood pressure and APOE genotype.

Study description

Background summary

Sporadic Cerebral Amyloid Angiopathy (sCAA) is one of the most frequent causes of intracerebral hemorrhage (ICH) and cognitive decline in the elderly. sCAA is characterized by the deposition of amyloid-β (Aβ) peptide in the capillaries, arterioles, and small and medium sized arteries of the cerebral cortex, leptomeninges and cerebellum, possibly due to impaired cerebral clearance of amyloid-β with increasing age. The clinical disease course of sCAA varies widely. Some patients suffer only from one ICH whereas others get multiple recurrent ICH. Some patients have rapid cognitive decline or frequent headaches and seizures whereas others have a relatively mild symptomatology. Except for APOE genotype, it is unknown which factors affect the disease course. With improving MRI techniques an increasing number of MRI markers have been found. The clinical relevance of these markers and their development over time is unclear.

Study objective

The overall aim of this study is to investigate clinical risk factors and MR markers that affect disease progression to gain more insight in targets for prevention and therapy and to better inform patients on prognosis.

Study design

The study design is a prospective follow-up study.

Study burden and risks

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. 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.
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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 >= 50y
2. Ability and willingness to provide written informed consent
3. Probable CAA based on the Boston criteria 2.0, and no family history of HCHWA-D, including CAA related inflammation

Healthy controls: age- and sex matched to the sCAA group, no history of neurological disease and free of substantial memory complaints

Exclusion criteria

1. Contra-indications for 3T/7T MRI as determined by the 7Tesla safety committee (exclusion for a subpart of the study).
2. Contraindications for lumbar puncture (exclusion for a subpart of the study).

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	14-02-2018
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO Date:	07-02-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-06-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-03-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	07-08-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO
Date: 12-03-2021

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 04-03-2022

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 15-04-2022

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 18-07-2022

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 16-12-2022

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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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	NL63256.058.17