The striped occipital cortex sign, a new MRI marker for sporadic cerebral amyloid angiopathy?

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The aim of this study is to investigate the presence of the stripped occipital cortex in patients with the sporadic form of CAA.

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

Summary

ID

NL-OMON43230

Source
ToetsingOnline

Brief title
he striped cortex, a new marke for CAA

Condition

- Central nervous system vascular disorders

Synonym
CAA

Research involving
Human

Sponsors and support

Primary sponsor: Neurologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: amyloid, angiopathy, MRI

Outcome measures

Primary outcome

The main parameter is the presence of the striped occipital cortex on 7T MRI.

Secondary outcome

Secondary parameters are other iron biomarkers such as microbleeds,

superficial siderosis, cortical subarachnoid haemorrhage and hypointensity of

the basal ganglia.

Study description

Background summary

One frequent cause of lobar (cortical) intracerebral hemorrhage (ICH) in the elderly is sporadic cerebral amyloid angiopathy (sCAA). sCAA is characterized by the deposition of amyloid-β peptide and degenerative changes in the capillaries, arterioles, and small and medium sized arteries of the cerebral cortex, leptomeninges, and cerebellum. Hereditary cerebral hemorrhage with amyloidosis-Dutch type (HCHWA-D) is an autosomal dominant form of CAA, in which the amyloid angiopathy is pathologically and biochemically similar to sCAA. The disease is characterized by (repeated) intracerebral hemorrhage and cognitive decline. Since in patients with HCHWA-D the genetic background is known it offers a unique opportunity to investigate in vivo the role of these vascular amyloid depositions on ICH progression, recurrence rate and outcome.
In the EDAN study (P11.094) we found a new MRI marker in patients with HCHWA-D (figure 1). This so called *stripped cortex sign* is present on 7T MRI in almost half of the HCHWA-D patients. The underlying pathophysiology of the stripped cortex is unknown. Probably it reflects amyloid associated iron depositions in the occipital region of the brain. It is unknown if the stripped occipital cortex is also present in the sporadic form of CAA. Because the diagnosis of sporadic CAA is difficult during life, a new biomarker could improve future diagnostic abilities for CAA.

Study objective

The aim of this study is to investigate the presence of the stripped occipital cortex in patients with the sporadic form of CAA.

Study design

Our study design is cross-sectional.

Study burden and risks

The potential risks are limited. The risks of 7T MRI are minimal (risk of every day life), because there are no consequences to the health of the participant. There is no benefit for the patients except for more insight into the underlying pathophysiology of the hemorrhages related to their disease. This study could eventually lead to a new biomarker for sCAA and improve the possibility of diagnosing sCAA during life.

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

Probable cerebral amyloid angiopathy according to the Boston criteria

Exclusion criteria

<18 jaar

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-11-2016
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	06-07-2016
Application type:	First submission
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	NL57720.058.16

Study results

Date completed:	02-11-2018
Actual enrolment:	15