Cerebral amyloid angiopathy fluid biomarkers evaluation - Alzheimer*s Disease (CAFÉ-AD)

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Our main objective is to develop and validate body fluid biomarkers that detect CAA in Alzheimer*s Disease patients during life.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON48320

Source
ToetsingOnline

Brief title
CAFE-AD

Condition

- Other condition
- Central nervous system vascular disorders

Synonym
Cerebral amyloid angiopathy; small vessel disease

Health condition

ziekte van Alzheimer

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NIH

Intervention

Keyword: Alzheimer's Disease, biomarkers, Cerebral amyloid angiopathy, cerebrospinal fluid

Outcome measures

Primary outcome

Biomarkers will first be evaluated for their suitability to serve as biomarkers

by univariate testing (t-test in case of comparison of two groups) or ANOVA

(comparison of more than two groups). Main comparisons will be between AD

patients with radiological evidence of CAA and Controls (recruited via the CAFÉ

project, file number 2017-3605) and between AD patients with radiological

evidence of CAA versus AD patients without radiological evidence of CAA.

Secondary outcome

Establishing correlations between the new neurochemical biomarkers on the one

hand and neuroimaging and neuropsychological

biomarkers on the other.

Study description

Background summary

Cerebral amyloid angiopathy (CAA), or the accumulation of amyloid beta protein (AbP) in the vasculature of the brain, is
increasingly recognized as a factor that contributes significantly to cognitive decline and higher dementia
Age. Biomarkers that can detect CAA during life are insufficiently available (only micro bleeding as very late
manifestation of CAA can be seen on MRI), and this contribution of CAA to

cognitive decline and dementia can have not been available so far.

Study objective

Our main objective is to develop and validate body fluid biomarkers that detect CAA in Alzheimer*s Disease patients during life.

Study design

Cohort study: identification and full validation of new neurochemical biomarkers in brain fluid (and blood)

Study burden and risks

Patients are asked to undergo an epidural, MRI and neuropsychological examination. For the epidural, people are asked to lie on their side with their legs pulled up. Next, with a thin needle in the lower back, the doctor will puncture the pouch where the brain fluid is. There is no spinal cord on the underside of the back, so there is no chance that it will be damaged. An epidural may cause headache symptoms in some people. These complaints usually disappear when you lie down. However, a small percentage of people can suffer for a few days. For younger people this can occur in 15-2% of the cases; in the elderly it is seen much less (<2%). The occurrence of serious consequences such as an infection or bleeding after an epidural is only extremely rare (<0.1%).

MRI is a technique for creating images of the body using a very strong magnet and radio waves.
The MRI consists of a tube of 1.5 m long with a diameter of 70 cm. This tube is open on both sides and illuminated on the inside. When examining the head, the patient is only partially in the MRI. The patient can talk to the lab technician and he can also see the patient via a video screen. The load for an MRI scan is approximately 45 minutes; in principle, nothing is noticed of the magnetic waves. One scan consists of several recordings .. This includes a lot of sound, for which one gets earplugs or headphones, but the sound of the MRI will be heard above the music. People with severe claustrophobia sometimes do not dare to take the MRI.

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

Diagnosis of Alzheimer*s disease made according to recent clinical criteria (26)
- Subjects are mentally competent to take a decision on participation.
- Written informed consent
- Age >55 years
- CDR 0.5 or 1.0

Exclusion criteria

Evidence of recent (< 3 months prior to planned lumbar puncture) neurological diseases other than Alzheimer*s disease (e.g. brain tumors, other vascular conditions (e.g. malformations), inflammatory or infectious disease)
- Evidence of recent (< 3 months prior to planned lumbar puncture) ischemic or hemorrhagic stroke
- Presence of blood coagulopathy, established by medical history
- Allergy to local anesthetic agents
- Contra-indication for lumbar puncture: medical history of compression of spinal cord, spinal surgery, skin infection, developmental abnormalities in lower spine

- Subjects who are currently participating in another study or have participated in a clinical study within the previous 30 days, based on their own report
- Subjects with a recent history of drug abuse
- Subjects who are part of the study staff personnel or family members of the study staff personnel
- Intracranial clips
- Contra-indications to MR Imaging:
o Claustrophobia
o Pacemakers and defibrillators
o Nerve stimulators
o Intraorbital or intraocular metallic fragments
o Cochlear implants
o Ferromagnetic implants
o Hydrocephalus pump
o Some intra-uterine device
o An iron wire behind the teeth placed before 1995
o Permanent make-up
o Tattoos above the shoulders
o Severe physical restriction / inability to be scanned, such as weight above 120 kg
o Difficulty with lying down for 45 minutes
o Light-sensitive epilepsy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-10-2020
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL71302.091.19