

CADASIL MRI on 7 Tesla

'a cortical exploration journey'

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON32570

Source

ToetsingOnline

Brief title

CADASIL MRI on 7 Tesla

Condition

- Congenital and hereditary disorders NEC
- Central nervous system vascular disorders

Synonym

CADASIL

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Van der Kamp fonds

Intervention

Keyword: brain, CADASIL, MRI

Outcome measures

Primary outcome

- Average thickness of the specific cortical layers, compared to those of the control subjects
- Focal abnormalities in the specific cortical layers
- Average wall thickness of the medial meningeal artery and the relation with patient age, compared to control subjects
- Shape of SLLs and relation with blood vessels
- Number of microbleeds and age distribution

Secondary outcome

n/a

Study description

Background summary

CADASIL (cerebral autosomal dominant arteriopathy with subcortical infarcts and leukoencephalopathy) is a dominantly inherited disease of the vessel walls which mainly manifests in the central nervous system and which leads to recurrent cerebral infarcts, migraine with aura and cognitive decline at young adult age to middle age. Imaging of the brain shows white matter hyperintensities, subcortical infarcts, microbleeds, subcortical lacunar lesions (SLLs) and cortical atrophy. Postmortal pathologic studies have shown that the cortical atrophy is mainly present in cortical layers 3 and 5, and that vessel wall thickening is present mainly in arterioles and leptomeningeal vessels. It has not been possible yet to demonstrate these findings in vivo. A 7 Tesla MRI-scanner has become available in the LUMC in 2007. The most important advantages of this scanner, compared to the current 1.5 Tesla and 3.0 Tesla scanners, are: an increased spatial resolution and an increased sensitivity for susceptibility artifacts, resulting in an improved detection

rate for diagnosing very small microbleeds.

Study objective

The aim of this study is to invite a new cohort of CADASIL patients for a 7 Tesla MRI scan. By doing this, we aim to get more insight into the pattern and development of cortical atrophy and vessel wall thickening in CADASIL patients of different ages. We also aim to make a better assessment of the prevalence, location and quantity of microbleeds in CADASIL and we aim to determine the exact anatomical substrate of the SLLs.

Study design

Patients will undergo an MRI scan of the brain on the 7 Tesla MRI scanner. By using a special surface coil, the level of cortical atrophy and leptomeningeal vessel wall thickening will be studied. Additionally, the subcortically located SLLs will be studied, and a characterisation of the microbleeds will take place.

Study burden and risks

This is an observational study, without invasive procedures. The study does not have any medical risks. Burden of participation for the participants will mainly consist of travelling to Leiden and cooperating with the MRI scan.

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

Confirmed NOTCH3 mutation

Age: 18 years or older

Mental competency

Exclusion criteria

MRI contraindications

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 17-03-2009

Enrollment: 35

Type: Actual

Ethics review

Approved WMO

Date: 24-12-2008

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date: 19-02-2009

Application type: Amendment

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date: 30-03-2009

Application type: Amendment

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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	NL25553.058.08