# 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 atrofy 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 obvervational 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

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

### Recruitment

NII

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-03-2009
Enrollment:	35
Туре:	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 CCMO ID NL25553.058.08