Vessel wall imaging in moymoya vasculopathy using intracranial MRI at 7.0 tesla

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Primary Objective: To study arterial vessel wall abnormalities of the intracranial vessels (circle of Willis and its main branches and the moyamoya vessels) in patients with MMV in comparison with age- and sex-matched subjects without known...

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

Summary

ID

NL-OMON47058

Source
ToetsingOnline

Brief title
The 7T-moyamoya study

Condition

- Central nervous system vascular disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
moyamoya, puff of smoke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Salaris onderzoeker: Hersenstichting/Tutein

Nolthenius-Oldenhof fonds/Johanna Kinderfonds

Intervention

Keyword: 7 Tesla, case control, moyamoya, vessel wall

Outcome measures

Primary outcome

The intracranial vessel wall (circle of Willis and its main branches and the moyamoya vessels) characteristics in MMV.

Secondary outcome

Secondary study parameters/endpoints

Establishing differences (e.g. in presence or absence of intracranial vessel wall abnormalities) in the vessel walls between the symptomatic and asymptomatic hemisphere in each individual patient and between children and adults.

Third study parameters/endpoints

The investigation of blood flow through the major arteries (circle of Willis and its main branches) and the moyamoya vessels (lenticulostriatal and leptomeningeal collaterals).

Other study parameters

The characterization the intracranial vessel wall, by evaluating the signal characteristics on multiple MRI sequences.

Study description

Background summary

Moyamoya vasculopathy (MMV) is a cerebrovascular disease in which a progressive bilateral occlusion of the supraclinoid internal carotid artery (ICA) and its proximal branches predisposes patients to stroke. The etiology is still unknown, and histopathological analyses of affected vessels show a combination of hyperplasia of smooth-muscle cells and luminal thrombosis. We propose a prospective study to investigate the intracranial vessel wall in moyamoya patients using a 7.0 tesla MR system. Based upon the intracranial vessel wall sequence, developed by the 7T group and used in an ongoing study (IVI study), a 7.0 tesla MR protocol will be developed and optimized for the visualization of the intracranial arterial wall in patients with MMV. With these results, we will gain insight in the underlying pathological vessel wall changes in MMV, which has not been reported on 7.0 tesla yet.

Study objective

Primary Objective: To study arterial vessel wall abnormalities of the intracranial vessels (circle of Willis and its main branches and the moyamoya vessels) in patients with MMV in comparison with age- and sex-matched subjects without known intracranial vessel wall disease, using 7T MRI.

Secondary Objective: To investigate differences in the vessel walls between the symptomatic and asymptomatic hemisphere in each individual patient and between children and adults.

Third Objective: To investigate the blood flow through the major arteries (circle of Willis and its main branches) and the moyamoya vessels (lenticulostriatal and leptomeningeal collaterals) and correlate this to the severity of the disease according to the Suzuki grading system with cerebral angiography. This will be achieved by bolus tracking after the administration of a Gadolinium-based contrast agent.

Fourth objective: To characterize the intracranial vessel wall, by evaluating the signal characteristics on multiple MRI sequences.

Study design

This study is designed as a single-center case-control observational non-therapeutic study. Intracranial vessel wall imaging will be performed with a 7T MRI scanner in patients with MMV, combined with standard clinical imaging of the brain. Results will be compared with the results of age- and sex-matched subjects. High resolution pre- and post-contrast (gadolinium) images of the

arterial vessel wall will be obtained using a dedicated intracranial vessel wall sequence at 7.0 tesla MRI. In addition to the vessel wall images, ultra-high resolution MR angiography of the intracranial vasculature (lumen) will be acquired. Furthermore, the MRA sequence will easily discriminate arteries from veins with opposite flow directions. The duration of the protocol will be approximately 60 minutes. The results of our study may enable characterization of the intracranial vessel wall pathology of MMV and help us to further investigate the etiology of MMV.

Baseline characteristics of all patients and control subjects will be collected during inclusion into our study.
Blood samples of all patients are already taken after first presentation for clinical purposes to verify the absence of renal dysfunction.
Healthy volunteers will be asked for known renal impairment. All patients will have their regular clinical work-up and treatment, independent of this study or its results.

We aim at an inclusion of 20 moyamoya patients, 10 children and 10 adults, in 4 years. A small group needs anesthesia during an MRI examination. Anesthesisized patients cannot be handled in the 7T scanner and will therefore not be included into this study. Since a similar MRI protocol is used in patients with suspected pituitary adenoma scanned in the context of clinical care, we will retrospectively include 20 of these patients after matching for age and sex. Furthermore, since we used a similar scanning protocol as in the included control groups in the *IVI* or *DIVA* studies, we would like to include these subjects in case we do not have a sufficient number of matches. In case we cannot find suitable matches from the aforementioned studies, we will include up to 10 healthy adult volunteers by asking the caregivers / partners of the patients to participate.

During the total scan, children can watch a movie or cartoon to have some distraction from the scanner noise. This might comfort the patient during the scan and may contribute to less motion artifacts.

The project will be performed in close collaboration with the department of Neurology and Neurosurgery and the department of Radiology (especially the 7T MR group) of the UMCU.

Study burden and risks

During the MRI, patients are exposed to strong magnetic fields and radio waves. In normal clinical practice, MRI is very
often used. There are no harmful effects on the human body determined. In some cases, people experience flashes of light, tingling and transient dizziness. These are always during the scan and disappear immediately after scanning. Implanted medical devices might become disturbed by the magnetic field. People with medical implants are therefore not considered for the study.

The gadolinium contrast agent is widely used for MR imaging exams in the clinical setting, and as such it is
administered to thousands of patients every year in our hospital. In some cases, an allergic reaction may occur. This
creates itching and nausea with possible red bumps on the skin. Almost always, these symptoms disappear after the
examination. It is seldom that medical treatment is necessary. At all times, there will be a doctor present as the contrast
agent is administered. Patients with a known allergy to the contrast agent gadolinium can not participate in this study.
If patients have renal problems, they can not participate in this study.

This is a group-related research: our patient population predominantly consists of children. Furthermore, MMV has a different course in children then in adults, with amongst others a higher progression rate. It is important to investigate differences in vessel walls between children and adults. The low risks of undergoing a MRI make the risk and burden for the subjects in proportion to the value of the research.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for pediatric patients
- Moyamoya vasculopathy
- Signed informed consent
- Age 12-18 yrs old
- MRI without anesthesia;Inclusion criteria for adult patients
- Moyamoya vasculopathy
- Signed informed consent
- Age 18-55 yrs old
- Legally competent
- MRI without anesthesia;Inclusion criteria for control subjects
- 12-60yrs old
- 7T MR imaging performed for suspected pituitary adenoma
- No known intracranial vessel wall disease or history of cerebrovascular events
If applicable:
- Legally competent
- Signed informed consent
- MRI without anesthesia

Exclusion criteria

For patients
- Allergic to gadolinium
- Impaired renal function (severe renal insufficiency, GFR <30ml/min/1.73m2, or nephrogenic systemis fibrosis/ nephrogenic fibrosing nephropathy (NSF/NFG))
- Impossibliity to undergo MRI (claustrophobia, implants or metal objects in or around the body)
- Pregnancy;For control subjects
- Allergic to gadolinium
- Impaired renal function (severe renal insufficiency, GFR <30ml/min/1.73m2, or nephrogenic systemis fibrosis/ nephrogenic fibrosing nephropathy (NSF/NFG))
- Impossibility to undergo MRI (claustrophobia, implants or metal objects in or around the body)
- Pregnancy
- Previous history of cerebrovascular diseases

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:	Recruitment stopped
Start date (anticipated):	14-08-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	10-09-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-04-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-09-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL45287.041.14