Diagnosing cerebral vasculitis using MR intracranial vessel wall imaging at 7.0 tesla

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

Summary

ID

NL-OMON47118

Source
ToetsingOnline

Brief title
DIVA

Condition

- Central nervous system vascular disorders
- Vascular disorders NEC

Synonym
cerebral vasculitis; vessel wall inflammation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: VIDI grant NWO

Intervention

Keyword: 7T, cerebral vasculitis, intracranial vessel wall, MRI

Outcome measures

Primary outcome

The main study parameters are the sensitivities and specificities of the

diagnosis based on the standard clinical work-up and the 7T MRI scans.

Secondary outcome

The secondary study parameter is the presence or absence of intracranial vessel

wall abnormalities in the two studied groups

Study description

Background summary

The cerebral vasculitides are a heterogeneous group of diseases. Early diagnostic discrimination between the cerebral vasculitides and other vessel wall diseases (vasculopathies) is, however, essential since they can have devastating consequences, often in relatively young patients, if not promptly and adequately treated.

After exclusion of non-inflammatory or cardiac embolic causes of stroke by extracranial and intracranial vessel assessment and cardiac investigations, an accurate diagnosis remains challenging due to limited sensitivity and specificity of different diagnostic modalities like Magnetic Resonance Imaging (MRI), Cerebrospinal Fluid (CSF) examination, angiography, and brain biopsy1, 2 for the diagnosis of cerebral vasculitis.

A diagnostic test with excellent properties for visualising the intracranial vessel wall could help making a correct and early diagnosis of cerebral vasculitis. Therefore, in the current study, we will develop a non-invasive method for the detection of cerebral vasculitis. Based upon the intracranial vessel wall sequence, developed by the 7T group and used in an on-going study (IVI study), a 7.0 tesla MR protocol will be developed and optimized for the visualization of the intracranial arterial wall in patients suspected of cerebral vasculitis. With our protocol we will be able to visualize both normal intracranial vessel wall as well as vessel wall abnormalities. Together with

the IVI-study and the PIVI-study, in which the intracranial causes of ischemic stroke of the anterior and posterior circulation, respectively, will be assessed, this study will provide better insight in the underlying pathological vessel wall changes in a large group of neurological patients.

Study objective

The main research question is to compare the diagnostic accuracy of 7T MRI for cerebral vasculitis, with the standard diagnostic practice (SDP). The true nature of the disease will be assessed for all patients at the end of the study by re-evaluation of the patients, assessing either response to treatment or recurrent symptoms (Reference standard, RS). The goal of the study is to compare both the sensitivities and specificities of the two diagnostic tests.

Study design

This study is designed as a single-center prospective case-control study. Intracranial vessel wall imaging will be performed with a 7T MRI scanner in patients suspected of cerebral vasculitis and healthy controls, combined with standard clinical imaging of the brain.

Baseline characteristics of all patients and healthy controls will be collected during inclusion into our study. The first 7T MRI exams in patients will be acquired during the symptomatic phase and before start of treatment for vasculitis (if applicable); the second 7T MRI exams will be performed after 6 months. Both the neurologist and radiologist (blinded for clinical status) will give a diagnoses to every individual patient based upon the standard clinical work-up or the 7T scan, respectively. This will be done at baseline and after 6 months. The 6 months scan and clinical work-up will allow them to assess the true nature of the disease and compare the sensitivity and specificity of the 7T MRI to that of the standard clinical work-up. The change in aspect of (one of) the artery (arteries) of the cerebral circulation after 6 months will allow a detailed assessment of the underlying cause of the disease, as well as possible changes due to received treatment (if applicable). The healthy controls will receive only one 7T MRI exam. Blood samples of all patients will be taken (if not already done 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 a yearly inclusion of 15-20 patients suspected of all forms of cerebral vasculitis. With this inclusion rate, 40 patients will be included in 3 years. An additional 40 healthy volunteers will be included during the three years of inclusion.

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. During their hospitalization some blood is usually taken by which we can determine whether they have kidney problems. If this is not the case, a blood sample will be taken, before the first MRI scan, for this study.

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

Inclusion criteria for healthy volunteers
- 18 years or older;Inclusion criteria for patients
- 18 years or older
- Ready for MRI before starting treatment of cerebral vasculitis(is applicable)
- Suspected cerebral vasculitis

Exclusion criteria

Exclusion criteria for healthy volunteers
- Allergic reaction to gadolinium
- Impaired renal function (severe renal insufficiency, GFR <30ml/min/1,73m2; or nephrogenic systemic fibrosis/ nephrogenic fibrosing nephropathy (NSF/NFG))
- Impossibility to undergo MRI (claustrophobia, implants or metal objects in or around the body)
- Pregnancy
- Previous history of cerebral vasculitis or other cerebrovascular diseases
- malign brain tumours of brain tumours treated with radiotherapy;Exclusion criteria for patients
- Allergic reaction to gadolinium
- Patients who are already treated with medication for cerebral vasculitis when included
- Patients with impaired renal function (severe renal insufficiency, GFR <30ml/min/1,73m2; or nephrogenic systemic fibrosis/ nephrogenic fibrosing nephropathy (NSF/NFG))
- Impossibility to undergo MRI (claustrophobia, implants or metal objects in or around the body)
- Pregnancy
-Malign brain tumour or brain tumours treated with radiotherapy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2013
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	19-08-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	07-08-2018
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24077
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL43684.041.13
OMON	NL-OMON24077