MRI measurements of the brain vessel walls in patients with cerebral vasculitis

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24077

Source
Nationaal Trial Register

Brief title
DIVA study

Health condition

Cerebral vasculitis, MRI, vessel wall

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Netherlands Organisation for Health Research and Development (ZonMw): VIDI Grant (91712322)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Our second objective is to compare the intracranial vessel wall abnormalities found in patients to the abnormalities found in healthy volunteers.

Our third objective is to investigate whether changes of the intracranial vessel wall occur between baseline and follow-up.

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

An accurate diagnosis of cerebral vasculitis remains challenging due to limited sensitivity and

specificity of different diagnostic modalities. 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. We hypothese that we can detect cerebral vasculitis in an early stage of the disease

Study design

Patients will undergo 2 7T MRI scans: one during hospital administration and one after 6 months.

Healthy volunteers will undergo 1 7T MRI scan at baseline.

Intervention

N/A

Contacts

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Eligibility criteria

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(if 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 tumour or 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 non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2013
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-02-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47118
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5633
NTR-old	NTR5748
CCMO	NL43684.041.13
OMON	NL-OMON47118

Study results

Summary results
Dieleman, Patterns of intracranial vessel wall changes in relation to ischemic infarcts, Neurology, 2014