

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24077

Bron

Nationaal Trial Register

Verkorte titel

DIVA study

Aandoening

Cerebral vasculitis, MRI, vessel wall

Ondersteuning

Primaire sponsor: University Medical Center Utrecht

Overige ondersteuning: Netherlands Organisation for Health Research and Development (ZonMw): VIDI Grant (91712322)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 biopsy^{1, 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.

Doel van het onderzoek

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 hypothesize that we can detect cerebral vasculitis in an early stage of the disease

Onderzoeksopzet

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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.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel: Parallel
Toewijzing: Niet-gerandomiseerd
Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 01-08-2013
Aantal proefpersonen: 80
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 10-02-2016
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47118
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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