MRI van de vaatwand op 3.0 en 7.0 tesla bij patiënten met een TIA of herseninfarct in de achterste circulatie

Geen registraties gevonden.

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Centraal zenuwstelsel vataandoeningen
Onderzoekstype	Observationeel onderzoek, met invasieve metingen

Samenvatting

ID

NL-OMON47288

Bron
ToetsingOnline

Verkorte titel
PIVI Studie

Aandoening

- Centraal zenuwstelsel vataandoeningen
- Arteriosclerose, stenose, vaatinsufficiëntie en necrose

Synoniemen aandoening
aderverkalking, atherosclerose

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Universitair Medisch Centrum Utrecht
Overige ondersteuning: Vidi grant NWO

Onderzoeksproduct en/of interventie

Trefwoord: herseninfarct, intracraniëel, MRI, vaatwand

Uitkomstmaten

Primaire uitkomstmaten

De aanwezig of afwezigheid van intracraniële vaatwandafwijkingen in de slagaders van de achterste hersencirculatie.

Secundaire uitkomstmaten

- Aantal intracraniële vaatwandafwijkingen gevonden met de vaatwand MRI-scan op 7.0 tesla in vergelijking met 3.0 tesla.

- Kenmerken van intracraniële vaatwand plaque, door verschillende MRI-signaal intensiteiten in in de plaque te onderscheiden.

- De klinische uitkomstmaten (vasculaire incidenten, niveau van handicap, huidige medicatie) verzameld tijdens de follow-up.

Toelichting onderzoek

Achtergrond van het onderzoek

Intracranial atherosclerosis is an important cause of ischemic stroke and transient ischemic attack (TIA). Development of atherosclerotic lesions occurs silently over a longer period of time, until they become symptomatic. Most non-invasive intracranial imaging methods (transcranial Doppler, MRA, CTA) are based on visualizing the lumen of the intracranial vasculature, thereby giving indirect information about the underlying vessel wall abnormalities caused by atherosclerosis. Because of arterial remodelling in which the luminal diameter remains equal despite the presence of an underlying atheroma, these lumenography techniques may result in underdiagnosis of intracranial atherosclerosis.

At the UMC Utrecht, within the 7.0 tesla group of Prof Luijten, an MRI sequence at 7.0 tesla was developed specifically for imaging of both healthy and abnormal intracranial vessel walls, and is currently being used in an on-going study (IVI Study) including patients with (transient) ischemia in the anterior cerebral circulation. Previous intracranial vessel wall MR imaging studies have mainly focused on the anterior circulation, where ischemia is most common. Ischemic stroke or TIA in the posterior circulation accounts for approximately

20 to 30% of all ischemic events. We hypothesize that arterial vessel wall abnormalities are also common in the posterior circulation, and are an important underlying cause of obstruction of arteries in the intracranial posterior circulation and subsequent ischemic stroke. Ultimately, for wide clinical application of intracranial vessel wall imaging, a translation has to be made to lower field strength MR scanners (3.0 tesla). Therefore, based on the 7.0 tesla intracranial vessel wall MR imaging protocol, we have developed a 3.0 tesla protocol for clinical implementation.

Doel van het onderzoek

The primary objective of the current study is to compare the presence or absence of arterial vessel wall abnormalities in the intracranial posterior circulation in patients with TIA or ischemic stroke with those of healthy controls using 7.0 tesla MRI.

The secondary objective is to assess the sensitivity of 3.0 tesla MRI to detect the vessel wall abnormalities visualised with 7.0 tesla MRI.

Tertiary objectives will be:
(i) characterization of intracranial arterial vessel wall atheroma, specifically unstable atheroma by evaluating the signal characteristics on multiple MRI sequences, including enhancement after contrast administration;
(ii) to compare the presence of intracranial arterial vessel wall abnormalities between patients with posterior and anterior circulation TIA or ischemic stroke, by combining our data with those of the on-going IVI Study;
(iii) to assess the possible correlation between the observed arterial vessel wall abnormalities and the occurrence of vascular events during follow-up.

Onderzoeksopzet

This study is a single-center, prospective case-control study. Intracranial vessel wall imaging will be performed with a 3.0 tesla and a 7.0 tesla MRI scanner in patients with TIA or ischemic stroke of the posterior circulation, and age- and sex-matched healthy controls, combined with standard clinical imaging of the brain on these platforms.

Baseline characteristics of all patients and healthy controls will be collected at inclusion into our study. All participating subjects (ischemic stroke/TIA patients and healthy controls) will undergo one 3.0 tesla and one 7.0 tesla MRI examination. In patients, both MRI examinations will be performed as soon as possible, but at the latest within 3 months, after the onset of ischemic symptoms. A minimum of 12 hours is taken in between both examinations, to make sure the contrast agent has washed out sufficiently. Clinical follow-up of the patients will be performed at 3 months and at 1, 2, and 3 year(s) after study inclusion, consisting of a brief survey conducted by telephone, and by

collecting data on recurrent vascular events. The healthy controls will not receive clinical follow-up.

Inschatting van belasting en risico

The results of this study will further unravel the contribution of intracranial atherosclerosis to posterior circulation ischemia, and its prevalence in patients with ischemic stroke as well as healthy individuals. The translation of 7.0 tesla intracranial vessel wall MR imaging to 3.0 tesla will make wide clinical application possible. There will be no direct benefits for the individual subjects participating in this study. But in the future we feel that the aforementioned MR measurements of intracranial atherosclerosis may be important to guide decisions about preventive treatment in patients with a high risk of (recurrent) stroke.

Risk assessment MRI:
To the best of our knowledge there are no short- or long-term risks involved of having an MRI scan. Participants are not requested to have any precautions or actions prior to or following to the MRI exam.

Risk assessment contrast agent:
The contrast agent Gadobutrol (Gadovist ®) is used. This is the standard contrast agent used in MR imaging examinations in the clinical setting, and as such it is administrated to thousands of patients every year at the UMC Utrecht. Gadovist is registered in the Register of Pharmaceuticals (RVG 25318). A standard amount of 0.1 mL/kg bodyweight will be administered.

Contactpersonen

Publiek

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NL

Wetenschappelijk

Universitair Medisch Centrum Utrecht

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NL

Locaties

Landen waar het onderzoek wordt uitgevoerd

Netherlands

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

>= 18 years of age;Additional inclusion criteria for ischemic stroke / TIA patients:
- TIA or ischemic stroke in the posterior circulation territory (= supplied via the vertebral and basilar arteries or their branches)
- Possibility to perform MRI scanning within 3 months after onset of relevant ischemic symptoms

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Allergic reaction to gadolinium or one of the constituents of its solution for administration
- Impossibility to undergo MRI (claustrophobia, implants or metal objects in or around the body)
- Severely impaired renal function (severe renal insufficiency, GFR < 30ml/min/1,73m2; or nephrogenic systemic fibrosis / nephrogenic fibrosing nephropathy (NSF/NFD))
- Pregnancy;Additional exclusion criteria for ischemic stroke / TIA patients:
- A TIA or ischemic stroke secondary to a surgical or interventional procedure
- Previous vertebrobasilar surgery or endovascular therapy

Additional exclusion criteria for healthy volunteers:
- History of cerebral events (e.g. ischemic stroke, TIA, hemorrhage)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, met invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel
Doel:	Diagnostiek

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	07-11-2013
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Goedgekeurd WMO

Datum:	16-07-2013
Soort:	Eerste indiening
Toetsingscommissie:	METC NedMec

Goedgekeurd WMO

Datum:	07-12-2016
Soort:	Amendement
Toetsingscommissie:	METC NedMec

Goedgekeurd WMO

Datum:	07-08-2018
Soort:	Amendement
Toetsingscommissie:	METC NedMec

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

ID: 20531
Bron: NTR
Titel:

In overige registers

Register	ID
CCMO	NL43704.041.13
Ander register	NTR5688 (www.trialregister.nl)
OMON	NL-OMON20531