MRI measurements of the brain vessel walls in patients with TIA or ischemic stroke of the posterior circulation.

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Intracranial atherosclerosis is an important cause of ischemic stroke and transient ischemic attack (TIA). Ischemic stroke or TIA in the posterior circulation accounts for approximately 20 to 30% of all ischemic events. We hypothesize that arterial...

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

Samenvatting

ID

NL-OMON20531

Bron
NTR

Verkorte titel
PIVI study

Aandoening

Atherosclerosis; ischemic stroke; TIA; MRI

Ondersteuning

Primaire sponsor: University Medical Center Utrecht, the Netherlands.
Overige ondersteuning: This work is supported by the Netherlands Organisation for Health Research and Development (ZonMw) with a VIDI Grant (91712322) and the European Research Council (ERC 2014 StG 637024 HEARTOFSTROKE) (Prof. J. Hendrikse).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The presence or absence of intracranial vessel wall abnormalities in arteries of the intracranial posterior circulation. Presence of atherosclerosis is defined as any irregularity of the arterial vessel wall.

Toelichting onderzoek

Doel van het onderzoek

Intracranial atherosclerosis is an important cause of ischemic stroke and transient ischemic attack (TIA). 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).

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.

Onderzoeksopzet

All participating subjects will undergo two MRI examinations, one on the 3.0 tesla MRI scanner, and one on the 7.0 tesla MRI scanner. In patients, both MRI examinations will be performed as soon as possible, but at the latest within 3 months, after symptom onset. A minimum of 12 hours is taken in between both examinations, to make sure the contrast agent has washed out sufficiently.

For measurement of clinical outcome after ischemic stroke or TIA a follow-up survey will be conducted at 3 months and at 1, 2 and 3 year(s) after inclusion in this study.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. ¡Ý 18 years of age.

Additional inclusion criteria for ischemic stroke / TIA patients:

1. TIA or ischemic stroke in the posterior circulation territory (= supplied via the vertebral and basilar arteries or their branches);

2. Possibility to perform MRI scanning within 3 months after onset of relevant ischemic symptoms.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation

in this study:

1. Allergic reaction to gadolinium or one of the constituents of its solution for administration;

2. Impossibility to undergo MRI (claustrophobia, implants or metal objects in or around the body);

3. Severely impaired renal function (severe renal insufficiency, GFR <30mL/min/1.73m2; or nephrogenic systemic fibrosis / nephrogenic fibrosing nephropathy (NSF/NFD));

4. Pregnancy.

Additional exclusion criteria for ischemic stroke / TIA patients:

1. A TIA or ischemic stroke secondary to a surgical or interventional procedure;

2. Previous vertebrobasilar surgery or endovascular therapy.

Additional exclusion criteria for healthy volunteers:

1. History of cerebral events (e.g. ischemic stroke, TIA, hemorrhage).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-07-2013
Aantal proefpersonen:	100

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47288
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5567
NTR-old	NTR5688
CCMO	NL43704.041.13
OMON	NL-OMON47288

Resultaten

Samenvatting resultaten
N/A