

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

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Atherosclerosis of the intracranial arteries has shown to be correlated with a high recurrent stroke risk. Our primary hypothesis is that intracranial vessel wall atheromas are an important underlying cause of obstruction of arteries of the anterior...

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

Samenvatting

ID

NL-OMON22252

Bron

Nationaal Trial Register

Verkorte titel

IVI study

Aandoening

Atherosclerosis, stroke, TIA, intracranial, vessel wall, MRI, magnetic resonance imaging.
Atherosclerose, herseninfarct, cerebraal infarct, intracraniaal, TIA, vessel wall, MRI.

Ondersteuning

Primaire sponsor: University Medical Center Utrecht

Overige ondersteuning: University Medical Center Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The presence or absence of intracranial atherosclerosis (intracranial vessel wall atheroma) in arteries of the anterior cerebral circulation in the studied groups (stroke patients and TIA patients).

Toelichting onderzoek

Achtergrond van het onderzoek

Atherosclerosis of the intracranial arteries has shown to be correlated with a high recurrent stroke risk. Our primary hypothesis is that intracranial vessel wall atheromas are an important underlying cause of obstruction of arteries of the anterior cerebral circulation. To test our hypothesis we will perform high resolution intracranial vessel wall imaging with a 7.0 Tesla MRI scanner in stroke patients and TIA patients.

For this single center prospective case control study, 50 stroke patients with occlusion of an anterior cerebral circulation artery on CT angiography and 50 TIA patients, all above 18 years of age and of all gender, will be recruited from the department of neurology of the UMCU. Our main study parameter is the presence or absence of intracranial atherosclerosis in an anterior cerebral circulation artery in the aforementioned groups; our secondary study parameters are signal characteristics of the intracranial vessel wall atheroma on multiple MRI-sequences. For collection of data, all stroke patients and TIA patients will undergo a first 7.0 Tesla MRI scan within 1 week after initial ischemic symptoms together with collection of baseline characteristics; a second 7.0 Tesla MRI scan will be performed 1 month after initial ischemic symptoms, together with one session of neuropsychological tests.

With these data we will not only be able to visualise the intracranial arterial vessel wall to obtain information on presence of atherosclerosis, but we could also ultimately provide valuable information regarding possible presence of an instable atheroma, by describing signal characteristics of these atheroma, and provide a basic understanding of the possible consequences of atherosclerosis of intracranial arteries.

Doel van het onderzoek

Atherosclerosis of the intracranial arteries has shown to be correlated with a high recurrent stroke risk. Our primary hypothesis is that intracranial vessel wall atheromas are an important underlying cause of obstruction of arteries of the anterior cerebral circulation. To test our hypothesis we will perform high resolution intracranial vessel wall imaging with a 7.0 Tesla MRI scanner in stroke patients and TIA patients.

Onderzoeksopzet

Stroke and TIA patients will undergo one 7 Tesla MRI scan approximately within 1 week after first symptoms, and a second 7 Tesla MRI scan together with neuropsychological tests 1 month after first symptoms.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

Postbus 85500
A.G. Kolk, van der
Utrecht 3508 GA
The Netherlands
+31 (0)88 7556687

Wetenschappelijk

Postbus 85500
A.G. Kolk, van der
Utrecht 3508 GA
The Netherlands
+31 (0)88 7556687

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Main inclusion criteria for stroke patients and TIA patients:

1. 18 years or older;
2. Male or female;
3. Ready for MRI scanning within 1 week after onset of ischemic symptoms.

Additional inclusion criteria for stroke patients:

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1. Ischemic symptoms conform PACI/TACI (Partial/Total Anterior Circulation Infarct);
2. CT acute stroke imaging protocol: area of ischemia of the anterior cerebral circulation territory based either on anatomical CT images or on CT perfusion images & occlusion of anterior cerebral circulation artery on CT angiography.

Additional inclusion criteria for TIA patients:

1. Transient ischemic symptoms (< 24 hours of duration) conform PACS/TACS (Partial/Total Anterior Circulation Syndrome);
2. No area of ischemia visualized on either anatomical CT images or on CT perfusion images.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria:

1. Stroke patients without occlusion of an artery of the anterior cerebral circulation on CT angiography;
2. Patients with a known cardiac cause of stroke;
3. Patients with a stroke secondary to surgical / interventional procedures;
4. Allergic reaction to gadolinium;
5. Patients with impaired renal function (severe renal insufficiency, $GFR < 30\text{ml/min/1,73m}^2$; or nephrogenic systemic fibrosis / nephrogenic fibrosing nephropathy (NSF/NFD));
6. Impossibility to undergo MRI (claustrophobia, implants or metal objects in or around the body).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 04-12-2009

Aantal proefpersonen: 100

Type: Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 25-11-2009

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47383

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2002
NTR-old	NTR2119
CCMO	NL28606.041.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON47383

Resultaten

Samenvatting resultaten

N/A