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

No registrations found.

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

Summary

ID

NL-OMON22252

Source
NTR

Brief title
IVI study

Health condition

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

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

Characterization of the intracranial vessel wall atheroma, specifically unstable atheroma, by MR signal on multiple MRI-sequences, and assessment of clinical consequences of intracranial atherosclerosis by evaluation of standard brain imaging and neuropsychological tests.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

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:

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.

Exclusion criteria

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 < 30ml/min/1,73m2; or nephrogenic systemic fibrosis / nephrogenic fibrosing nephropathy (NSF/NFD));

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-12-2009
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-11-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47383
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A