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

No registrations found.

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

Summary

ID

NL-OMON20531

Source
Nationaal Trial Register

Brief title
PIVI study

Health condition

Atherosclerosis; ischemic stroke; TIA; MRI

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Number of vessel wall abnormalities in the intracranial vessel wall MRI scan at 7.0 tesla as compared to 3.0 tesla.

2. Characteristics of intracranial vessel wall atheroma, by discriminating different MRI signal intensities in the vessel wall atheroma.

3. The clinical outcome measures (e.g. occurrence of vascular events, level of handicap, current medication) collected during follow-up.

Study description

Study objective

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.

Study design

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.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-07-2013
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion
Date: 27-01-2016
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47288
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A