Improved prediction of recurrent stroke and detection of small volume stroke

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1) To identify clinical and imaging predictors of recurrent stroke; 2) To improve early detection of small volume stroke with admission computed tomography perfusion (CTP) in patients with suspected acute ischemic stroke with small volume stroke or…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON48750

Source
ToetsingOnline

Brief title
ENCLOSE

Condition

- Cardiac arrhythmias
- Central nervous system vascular disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
ischemic stroke; brain infarction

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: NWO TTW (voorheen STW) / Hartstichting

Intervention

Keyword: (recurrent) stroke, magnetic resonance imaging, prognosis, spectral computed tomography (CT)

Outcome measures

Primary outcome

• Stroke recurrence rate at 2 years;

• Presence and volume of acute ischemic lesions on follow-up diffusion weighted imaging (DWI) MRI.

Secondary outcome

• Stroke recurrence rate at 2 days, 10 days and 90 days;

• Cardiac thrombus on trans-thoracic echography (TTE), trans-esophageal echography (TEE) or ECG-gated cardiac CTA in patients with suspected thrombus on admission CTA (as part of standard clinical practice, patients with suspected cardiac thrombus on admission CTA and patients without an obvious other cause of ischemic stroke will be referred to a cardiologist to confirm or detect a cardioembolic source with trans-thoracic echography followed by trans-esophageal echography if necessary or additional ECG-gated cardiac CTA);

• Atherosclerotic plaque composition of the extracranial internal carotid artery or carotid bifurcation on contrast enhanced MRI;

• 90 day modified Rankin scale.

Study description

Background summary

Over 20.000 people suffer an ischemic stroke in the Netherlands each year.

Large artery occlusions are easy to identify and can be treated with endovascular clot removal. 70% of patient will however suffer from a more distal occlusion resulting in small volume stroke or a transient ischemic attack (TIA). Small ischemic lesions are hard to detect with current acute stroke protocols. TIA and small volume stroke patients, are at an increased risk for recurrent stroke, making immediate diagnosis critical. Because thrombo-embolic sources often cause these strokes, identifying and treating the underlying aetiology has the potential to radically lower the risk of recurrence and improve the outcome of these patients.

Study objective

1) To identify clinical and imaging predictors of recurrent stroke;
2) To improve early detection of small volume stroke with admission computed tomography perfusion (CTP) in patients with suspected acute ischemic stroke with small volume stroke or no ischemia on admission imaging.

Study design

Prospective, multicenter cohort study.

Study burden and risks

All imaging and clinical data of patients with written informed consent will be collected during a period of 2 years, to determine the rate of stroke recurrence and identify clinical and imaging predictors of stroke recurrence. As part of standard care, patients will be contacted for follow-up evaluation by a trained stroke nurse or neurologist (resident) at 90 days. For this study, patients will be asked for a second follow-up evaluation by telephone at 2 years.
Patients with small volume stroke or no ischemia on admission imaging will be asked for informed consent to undergo MRI of the brain within 48 hours after admission. If an MRI of the brain is performed within the scope of standard care within 48 hours after admission, the data of this clinical MRI scan will be used and the patient does not need to undergo an additional MRI scan.
The risk of the MRI is minimized by careful screening. The risk of severe allergic reaction due to administration of gadolinium is extremely low (0.006%).
The additional MRI will result in more certainty regarding the presence of ischemic stroke. Patients who are not able to understand or express their informed consent, will not be asked for the MRI part of this study.
Informed consent will be asked separately for 1) the use of the admission CT data, patient information, and clinical follow-up; and 2) the acquisition of the additional follow-up MRI (if applicable).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Age >=18 years;
• Time from symptom onset until imaging is <9 hours*;
• Clinical diagnosis of acute ischemic stroke or TIA;
• Informed consent from patient or family after the admission scan (unless the patient died).
* Patients who awaken with stroke symptoms can only be included if they went to sleep without any stroke symptoms and the time from going to sleep until imaging is less than 9 hours.;To be eligible for a follow-up MRI, a subject must meet all of the following criteria:
• Occlusion distal to the A2 segment of the anterior cerebral artery, occlusion distal to the M1-M2 bifurcation of the middle cerebral artery, occlusion of the posterior cerebral artery (no occlusion of the basilar artery) or no visible occlusion as determined on the admission CTA

scan;
• No contraindications for MRI.

Exclusion criteria

• Patients with another diagnosis such as intracerebral hemorrhage, subarachnoid hemorrhage or tumor;
• Patients with known contrast allergy or renal failure.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-01-2018
Enrollment:	720
Type:	Actual

Ethics review

Approved WMO Date:	24-10-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	11-04-2018
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO Date:	21-02-2019
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL62233.041.17