# Mind the Heart: diagnostic yield of cardiac CT-angiography in the acute phase of ischemic stroke

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HypothesisWe hypothesize that a CTA of the heart and entire aortic arch, performed in the acute phase (defined as within window for reperfusion therapy through thrombolysis or thrombectomy) in patients with acute ischemic stroke, is superior to...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Cardiac disorders, signs and symptoms NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON50352

**Source**
ToetsingOnline

**Brief title**
Mind the Heart

### Condition

- Cardiac disorders, signs and symptoms NEC
- Central nervous system vascular disorders
- Embolism and thrombosis

**Synonym**
Ischemic stroke, stroke

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Neurologie

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** cardiovascular diseases, Cerebrovascular stroke, heart

## Outcome measures

### Primary outcome

Proportion of acute ischemic stroke patients in which a high-risk cardio-aortic source is established with CTA compared to transthoracic echocardiography. For specification of cardio-aortic causes of ischemic stroke, please see C1 onderzoeksprotocol 'Main study parameter/endpoint'.

### Secondary outcome

Comparison of two diagnostic strategies (CTA vs TTE), expressed as proportion of patients in which a high-risk cardio-aortic source is established with CTA, compared to TTE (this analysis also includes patients who did not undergo TTE).

Inter-observer variability of interpretation of cardio-aortic CTA images

Cardiac treatment received within 90 days and 2 years, including time between onset of stroke and cardio-aortic treatment

Recurrent stroke within 90 days and 2 years

Modified Rankin Scale (mRS) score at 90 days (standard care) and 2 years (for the purpose of the study)

Male/female differences in occurrence, subtype, treatment and outcome of cardio-aortic causes of acute ischemic stroke

Proportion of cardiac thrombi, identified on CTA of the heart, which dissolve on sequential imaging at 24 hours and 7 days after initial CTA imaging

# Study description

### Background summary

Stroke is the second leading cause of mortality and disability worldwide. About one third of ischemic strokes are caused by cardioembolism. Early determination of stroke etiology is essential for three reasons:
1. Detection of etiology is more likely to succeed directly after the stroke (*smoking gun*). For instance, an intracardiac thrombus may vanish after intravenous thrombolysis.
2. The choice of secondary prevention depends on the etiology. Cardioembolic stroke generally requires treatment with oral anticoagulation.
3. The risk of recurrence is highest early after the initial stroke. Early detection of the cause can prevent recurrent strokes.

The current acute ischemic stroke work-up includes a combination of brain imaging (CT or MRI), imaging of the intra- and extracranial arteries (CTA, MRA or ultrasound), cardiac rhythm monitoring (ECG, Holter) and imaging of the heart (ultrasound).

In the acute phase (currently defined as 24 hours after symptom onset) patients undergo a CTA of the brain and cervical arteries. In most hospitals, the heart and aortic arch are not generally included in this CTA. Recently, the AMC started including the heart and aortic arch as part of standard care. Echocardiography is performed days to weeks after the initial stroke, on an elective basis. Stroke patients receive ECG and/or rhythm monitor, but these auxillary investigations can't identify all cardiac causes. All these investigations are time-consuming, sometimes invasive, expensive, and may delay adequate treatment.

In addition, ideally these often very ill stroke patients should undergo as few burdensome investigations as possible. Therefore, a *one-stop-shop* for diagnosis and determination of the underlying etiology in the acute phase in patients with acute ischemic stroke would be an important innovation of stroke care.

### Study objective

Hypothesis
We hypothesize that a CTA of the heart and entire aortic arch, performed in the acute phase (defined as within window for reperfusion therapy through thrombolysis or thrombectomy) in patients with acute ischemic stroke, is superior to echography for detecting cardio-aortic sources of acute ischemic stroke.

Research questions
1. Does a CTA of the heart and aortic arch in the acute phase in patients with acute ischemic stroke have a higher diagnostic yield than transthoracic echocardiography for diagnosis of high-risk cardio-aortic causes of acute ischemic stroke?
2. What is the inter-observer variability of interpretation of cardio-aortic CTA images in patients with acute ischemic stroke?
3. Does implementation of a CTA of the heart and aortic arch in the acute phase result in treatment of cardio-aortic abnormalities?
4. Are there differences between males and females in terms of occurrence and subtype of cardio-aortic causes of acute ischemic stroke, treatment choice and outcome?
5. What is the proportion of cardiac thrombi, identified on CTA of the heart, which dissolve on sequential imaging at 24 hours and 7 days after initial CTA imaging?

**Study design**

Prospective observational single center cohort study. Site: AMC.
Patients will undergo a standard care ECG triggered CTA in the acute setting, including the heart, aortic arch, cervical and intracranial arteries - prior to the start of reperfusion therapy. Patients will also receive standard care ECG, Holter, transthoracic echocardiography. In the study the yield of CTA will be systematically compared to transthoracic echocardiography for detection of cardio-aortic causes of ischemic stroke.

In a proportion of patients (circa 25%) in whom transthoracic echocardiography is not performed as part of standard care, transthoracic echocardiography will be performed as part of research, after informed consent has been obtained.
In a small proportion of patients (circa 8%), those who have a cardiac thrombus as identified on CTA of the heart, sequential CTA of the heart will be performed at 24 hours and, for patients with a persisting thrombus, at 7 days after initial imaging, after informed consent has been obtained.

Please also see C1 onderzoeksprotocol 4.2 Study procedures.

**Study burden and risks**

Burden and risks associated with participation are minimal.

Clinical and imaging patient data which are obtained as part of standard care will be used, after written informed consent. As part of standard care, patients will be contacted for a follow-up evaluation by a trained stroke nurse at 90 days. For this study, patients will be contacted once by phone after 2 years for a conversation of maximum 15 minutes. There are no psychologically intrusive questions.

In a proportion of patients (circa 25%) in whom transthoracic echocardiography is not performed as part of standard care, transthoracic echocardiography will be performed as part of research, after informed consent has been obtained.
In a small proportion of patients (circa 8%), those who have a cardiac thrombus as identified on CTA of the heart, sequential CTA of the heart will be performed at 24 hours and, for patients with a persisting thrombus, at 7 days after initial imaging, after informed consent has been obtained.

Please also see C1 onderzoeksprotocol 7.4 Benefits and risks assessment, group relatedness.

## Contacts

**Public**
Selecteer

Meibergdreef 9
Amsterdam 1105AZ
NL
**Scientific**
Selecteer

Meibergdreef 9
Amsterdam 1105AZ
NL

## 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;
• Clinical diagnosis of acute ischemic stroke;
• Candidate for reperfusion therapy (thrombolysis, thrombectomy);
• Informed consent from patient or representative after the standard practice CTA of heart, aortic arch, cervical arteries and brain.

### Exclusion criteria

• Patients with another diagnosis such as transient ischemic attack (TIA), intracerebral hemorrhage, subarachnoid hemorrhage or tumor;
• No CTA of the heart performed;

## Study design

### Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 04-06-2018 |
| Enrollment: | 450 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 14-05-2018 |

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| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 06-07-2018 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 23-10-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 23-12-2020 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 21-04-2021 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

# 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 | NL64139.018.18 |