Mind the Heart 2: Detecting cardiac thrombi in acute ischemic stroke on cardiac CT versus transoesophageal echocardiography

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a) Determine whether acute cardiac CT has a higher probability of diagnosing LA thrombi compared to TEE or repeated cardiac CT in the subacute phase of ischemic stroke by assessing the rate at which LA thrombi dissolve in the first days after...

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

Summary

ID

NL-OMON56542

Source
ToetsingOnline

Brief title
MtH-DETECT

Condition

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

Synonym
Ischemic stroke, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Hartstichting (¤30.000)

Intervention

Keyword: Cardiac CT, Cardiac thrombi, Ischemic stroke, Transoesophageal echocardiography

Outcome measures

Primary outcome

1) Rate at which LA thrombi visualized on acute cardiac CT dissolve in the

first days after ischemic stroke.

2) False-positive rate for detection of left atrial thrombi on acute cardiac CT

compared to TEE.

Secondary outcome

- Secondary outcomes include other pre-defined high-risk and non-high-risk

sources of embolism on cardiac CT and TEE, which will also be systematically

assessed according to predefined criteria.These sources of embolism are:

o Left ventricular thrombus,

o Prosthetic valve abnormalities (pannus or thrombus),

o Signs of endocarditis (e.g., valvular vegetations),

o Atrial myxoma,

o Papillary fibroelastoma,

o Sign of myocardial infarction,

o Signs of rheumatic valvular disease (mitral stenosis),

o Left atrial appendage morphology,

o Left atrial appendage slow-flow,

o Left atrial (appendage) volume,

o Atrial diverticulum,

o Left ventricular apical aneurysm,

o Patent foramen ovale,

o Atrial septal defect,

o Aortic atherosclerotic plaque, including size, ulceration and composition

- We will assess the clinical impact of detecting cardiac thrombi and other sources of embolism on acute cardiac CT and TEE, including any impact on stroke etiology according to Trial of Org 10172 in Acute Stroke Treatment (TOAST) criteria.3 Any complications resulting from cardiac CT (i.e. contrast allergy and contrast induced nephropathy) and TEE will be recorded.

Study description

Background summary

Cardiac CT acquired during the acute stroke imaging protocol (acute cardiac CT) has recently been shown to have a superior diagnostic yield than transthoracic echocardiography, which is currently the most commonly used method to screen for structural sources of cardioembolism in patients with acute ischemic stroke. The most common finding on acute cardiac CT are cardiac thrombi located in the left atrium (LA) and specifically the left atrial appendage (LAA). The higher diagnostic yield of acute cardiac CT compared to TTE is partially explained because CT allows for better visualization of the LAA, but also because cardiac thrombi may dissolve in the first days after stroke. Whether acute cardiac CT is the optimal diagnostic modality for LA thrombi in stroke patients is unknown, since data comparing it to transoesophageal echocardiography (TEE), which is the reference standard to detect LA thrombi, are lacking. The general hypothesis of this study is that acute cardiac CT is the optimal method to detect LA thrombi in ischemic stroke patients, since TEE can miss LA thrombi that dissolve in the first days after stroke.

Study objective

a) Determine whether acute cardiac CT has a higher probability of diagnosing LA thrombi compared to TEE or repeated cardiac CT in the subacute phase of ischemic stroke by assessing the rate at which LA thrombi dissolve in the first days after ischemic stroke occurrence.
b) Determine the positive predictive value of acute cardiac CT compared to TEE for the detection of LA thrombi.

Study design

Prospective, multi-centre, observational cohort. Patients will undergo acute cardiac CT as part of routine clinical care. Patients will undergo transoesophageal echocardiography in Amsterdam UMC for research purposes and in UZ Leuven as part of standard clinical practise. Thereby, patients will undergo repeated cardiac CT for research purposes in both centers. The repeated cardiac CT is essential to determine the rate at which cardiac thrombi dissolve and , in case a thrombus is not visualized on TEE, to make the distinction between a false-positive findings on the initial cardiac CT and a thrombus which has dissolved.

Study burden and risks

Clinical and imaging patient data which are obtained as part of standard care will be prospectively collected after written informed consent. Patient with a LA thrombus on acute cardiac CT will undergo TEE in Amsterdam UMC for research purposes after obtaining written informed consent and in UZ Leuven as part of standard clinical practise. TEE is semi-invasive and associated with a small risk of major complications (<0.2%). Patients will also be exposed to additional radiation (1.4 mSv) due to sequential cardiac CT after TEE. The Radiation Dose Committee deemed this to be a intermediate risk. In a small minority of patients (<10%), another cardiac CT will be acquired 2 minutes after this sequential cardiac CT to ensure a clear, final assessment of the presence of an atrial appendage thrombus. This will result in a total additional radiation of around 3 mSv for the two additional cardiac CT*s. The Radiation Dose Committee deemed this to be an intermediate risk. As part of standard care, patients will be contacted for follow-up evaluation by a trained stroke nurse at 90 days. This information will be used in the current study.
As a result of ischemic stroke, some patients become incapacitated to an extent they are unable to give informed consent. In these cases, the legal representative will be asked for informed consent. Decreased level of consciousness or aphasia are typical clinical characteristics of cardioembolic stroke. Therefore, it is pivotal to also include incapacitated acute ischemic stroke patients. Excluding these patients from the study would render the study non-representative of the study*s target population (acute ischemic stroke patients with cardioembolic stroke due to LA thrombus).

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

Population (base)
Patients 18 years or older with acute ischemic stroke and a left atrial thrombus detected on cardiac CT acquired during the initial stroke imaging protocol at Amsterdam UMC, location AMC.

Inclusion criteria
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Age 18 years or older
• Clinical diagnosis of acute ischemic stroke
• Written informed consent from patient or representative
• Radiological diagnosis of cardiac thrombus in the LA, including the LAA, on

cardiac CT acquired during the initial stroke imaging protocol.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Patients with a diagnosis other than acute ischemic stroke, such as: transient ischemic attack, intracerebral haemorrhage, subarachnoid haemorrhage, epilepsy, tumor.
• Absolute contraindication for TEE:
o Perforated viscus
o Esophageal stricture
o Esophageal tumor
o Esophageal perforation, laceration
o Esophageal diverticulum
o Active upper GI bleed
• Absolute contraindication for repeat cardiac CT
o Documented previous severe reaction to iodinated contrast media, including anaphylaxis, angioedema and bronchospasm.
o Severely impaired kidney function defined as estimated glomerular filtration rate of 30 mL/min/1.73 m2.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-09-2024
Enrollment:	14
Type:	Anticipated

Ethics review

Approved WMO Date:	28-12-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-02-2025
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	NL84141.018.23