Implementing dynamic cardiac CT in a standardized diagnostic work-up for native valve infective endocarditis.

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To prospectively evaluate the diagnostic accuracy of dynamic cardiac CT in addition to and in comparison with TEE in unselected patients with a clinical suspicion of native valve endocarditis.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Endocardial disorders
Study type	Observational non invasive

Summary

ID

NL-OMON51466

Source
ToetsingOnline

Brief title
Endocarditis CT

Condition

- Endocardial disorders
- Bacterial infectious disorders

Synonym
Endocarditis. Heart valve infection

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac CT, Endocarditis

Outcome measures

Primary outcome

The diagnostic accuracy of dynamic cardiac CT in additon to and in comparison

with TEE.

Secondary outcome

-Cost effectiveness analysis of dynamic cardiac CT in addition to and in

comparison with TEE.

-Retrospectively allocated treatment strategy based dynamic cardiac CT in

addition to and in comparison with TEE.

-Interobserver variability of dynamic cardiac CT regarding the diagnosis NVE.

Study description

Background summary

Infective endocarditis (IE) is a disease with a high in-hospital mortality, morbidity, and complication rate . The diagnosis of IE is often challenging and is based on imaging criteria amongst others. According to the current European and Dutch guidelines transoesophageal echocardiography (TEE) is frequently used. TEE is a semi-invasive procedure sometimes requiring sedation. However, current literature shows that the diagnostic accuracy of dynamic cardiac computed tomography (CT) is more or less comparable to TEE in a selected population of mostly pre-operative and complicated IE patients.

Study objective

To prospectively evaluate the diagnostic accuracy of dynamic cardiac CT in addition to and in comparison with TEE in unselected patients with a clinical suspicion of native valve endocarditis.

Study design

Single centre, prospective cohort study.

Study burden and risks

There is a small risk for patient as patients will undergo a dynamic cardiac CT. For a dynamic cardiac CT the average radiation dose is 3 millisieverts and average 60-70 ml of iodine contrast will be used. Futheremore, all patients will be contacted once by telephone six month after hospitalization to screen for complications.

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

-Patients aged > 18 years old hospitalized at the Radboudumc with a clinical suspicion of infective endocarditis
-Positive blood cultures
-Clinical indication for TEE, according to current guideline recommendations

Exclusion criteria

-Pregnancy or breastfeeding
-Prosthetic heart valve
-Cardiovascular implantable electronic device
-Body mass index > 35 kg/m2
-Glomerular filtration rate < 30 mL/min/1.73 m2
-Previous allergic reaction to iodine contrast dye

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-04-2023
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	CT scan
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-08-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL80816.091.22