Dual energy CT for comprehensive cardiac imaging in patients suspected of coronary artery disease

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	-

Summary

ID

NL-OMON26825

Source
Nationaal Trial Register

Brief title
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Health condition

Coronary artery disease/ coronaire hartziekte
Dual energy CT
Perfusion imaging/ Perfusie beeldvorming

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: NWO - persoonlijke beurs (VENI) Rozemarijn Vliegenthart

Intervention

Outcome measures

Primary outcome

The diagnostic accuracy of the rest coronary CT angiography in combination with stress dual energy CT in comparison to SPECT and invasive coronary angiography in patients with a intermediate to high risk of coronary artery disease.

Secondary outcome

Diagnostic accuracy of myocardial ischemia detection using DECT in comparison to SPECT ischemia detection in patients with a intermediate to high risk of coronary artery disease, radiation dose.

Study description

Background summary

The purpose of this study is to validate a comprehensive CT protocol to determine hemodynamically significant coronary artery disease. Combined DECT and CT angiography could provide a one-stop shop in cardiac imaging in the future. The diagnostic accuracy of DECT plus CT angiography will be determined in comparison to gold standard, SPECT and ICA. This proposal will provide crucial data evaluating this potential. The disadvantages of this study are the radiation dose and the administration of contrast agents and beta-blocker. In accordance with limited reports so far, we determined that the radiation burden for comprehensive cardiac CT imaging will not exceed 10 mSv for each individual patient, which can be checked real time during the CT examination. Because of the administration of contrast agent, patients with a poor renal function (eGFR< 50 ml/min) and iodine allergy will be excluded. Patients with healthy renal function are not expected to have negative effects due to the contrast administration. The scans will be made on a third generation dual source scanner (Force, Siemens Medical Systems, Forchheim, Germany).

Study objective

The aim of this study is to validate a new CT technique (dual energy CT) in the ability to detect myocardial perfusion defects in patients suspected of having coronary artery disease. A combination of CT angiography and stress dual energy will be compared to gold standard diagnosis, SPECT and invasive coronary angiography.

Study design

Not applicable

Intervention

Dual energy CT scan and CT angiography

Contacts

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Eligibility criteria

Inclusion criteria

• Stable angina pectoris

• Nuclear MPI within the last 60 days

• Scheduled for ICA

• Patients must provide consent in writing after proper education and discussion with the treating physician and/or research physician

• 50 years or older

Exclusion criteria

• Cardiac rhythm other than sinus

• Second or third degree atrioventricular block

• Prolonged QT-time

• Sick-sinus syndrome

• Asthma or chronic obstructive pulmonary disease

• Contraindications for iodine contrast

• Thyroid gland disorders

• Renal insufficiency (eGFR < 50 ml/min)

• Rest heart > 65 bpm and contraindications for beta-blocker

• Severe arterial hypertension (>220/120 mmHg)

• Severe arterial hypotension (<80/40 mmHg)

• Unable to stay in a supine position

• Morbidly obese (Body mass index >35)

• Severe physical deterioration due to concomitant illness

• Language barrier

• Acute coronary syndrome

• Pregnancy

• Claustrophobia

• Using of persantin, theophylline, digoxin or verapamil, if temporarily stopping (48h) is not possible

• Contraindications for CTA: presence of pacemaker or ICD leads, AF, pregnancy, BMI >35 kg/m2, prosthetic heart valve

• Previously documented myocardial infarction/PCI/CABG

Study design

Design

Intervention model: Other

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2016
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5634
NTR-old	NTR5749
Other	: ABR 53631

Study results

Summary results

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