

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

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Primary Objective: • To study the accuracy of a combined CT angiography and DECT for complete imaging of CAD compared to the reference standard, ICA and SPECT MPI.

Secondary Objective(s): • To compare DECT analysis in the detection of perfusion...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Coronary artery disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON43905

### Source

ToetsingOnline

### Brief title

DECT for cardiac imaging

### Condition

- Coronary artery disorders

### Synonym

Coronary artery disease, myocardial ischemia

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** persoonsgebonden beurs (VENI) prof. dr. R. Vliegenthart

## Intervention

**Keyword:** Coronary artery disease, Dual energy CT, myocardial perfusion imaging

## 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

Heart diseases are a leading cause of mortality in the developed world. In the Netherlands 30% of all deaths are caused by cardiac diseases. Despite the slow gradual decline seen in cardiac mortality over the past decade, CAD, represented as the number of hospitalizations, diagnostic and therapeutic procedures, number of disability-adjusted life-years (DALYs) and overall health care expenses, continues to pose serious concerns about the current and future social and economic burden, both nationally and worldwide. In 2007, there were 648,300 patients known with coronary artery disease (CAD) in the Netherlands. The pathogenesis of CAD has been studied extensively, and the underlying mechanism is well known. It involves the progression of fatty streaks in the intima of the coronary arteries to fibrous and fatty plaques, which can eventually calcify. These plaques partially block the lumen of the coronary arteries, causing a stenosis. In a state of exercise, such a stenosis can hamper blood flow and result in hypoperfusion of parts of the myocardium. Patients can experience this, for instance, as chest pain (angina pectoris). In case of severe narrowing of the coronary artery, the reduced perfusion of the myocardium can even occur in rest. Early detection and aggressive treatment of vulnerable patients remain the

ultimate goals of cardiovascular clinicians. Until recently the most common method used in CAD detection was invasive coronary angiography (ICA), however in recent years computed tomography angiography (CTA) has become an accurate alternative for excluding significant CAD. Still, it is surprisingly difficult to determine whether detected coronary artery stenoses actually results in ischemia, especially in the intermediate stenosis range (30-80%). Correct determination of these stenoses generally requires both morphological (anatomical) and functional (perfusion) data. Given this combination of requirements, many attempts have been made to combine coronary CTA with functional studies such as PET and SPECT myocardial perfusion imaging (MPI). However, in this scenario, patients are required to undergo at least two diagnostic studies in order to acquire combined cardiac workup, which is not only inconvenient for the patient but also subjects the patient to a high radiation dose, SPECT approximate dose of 8-10 mSv. In DECT stress imaging, acquisition is performed in one phase. Other studies are investigating dynamic perfusion CT, however at a (much) higher radiation dose. The ideal workup for a CAD patient would be a single non-invasive test providing a conclusive diagnosis. No one technique currently used in myocardial perfusion imaging provides both morphological and functional imaging in a consistent and reliable manner. New dual-source computed tomography (DSCT) applications hold great potential to acquire both functional and morphologic information in one scan. DSCT scanners have two detector elements, providing the ability to acquire cardiac images at multiple energy levels simultaneously. Dual energy CT (DECT) exploits the fact that human tissue and iodine-based contrast material can be distinguished using X-ray beams with different energy levels. The assessment of myocardial blood supply can be performed using HU and iodine distribution analysis, which enables detection of myocardial ischemia. The prospect of combined DECT analysis and coronary CTA makes CT a promising competitor for future patient workup, applying DECT to provide functional information and CTA to provide morphologic information. In the future, a negative CT would prevent both SPECT and ICA (radiation burden and invasive technique), where a positive CT would result in PCI or CABG. Recent study of Patel et al. have shown that only 41% of patients with a positive stress test (high risk) has obstructive coronary artery disease at elective ICA. One of the major disadvantages of ICA is the inherent risk of invasive procedures. ICA can lead to serious vascular and bleeding complications, especially in the growing population of (very) obese patients or in the presence of comorbidities, with reported complication rate up to 7.5%.

## **Study objective**

Primary Objective:

- To study the accuracy of a combined CT angiography and DECT for complete imaging of CAD compared to the reference standard, ICA and SPECT MPI.

Secondary Objective(s):

- To compare DECT analysis in the detection of perfusion defects compared to SPECT MPI.

- To compare the radiation dose DECT + CT angiography to SPECT MPI and ICA.

## Study design

Prospective single center study

## Study burden and risks

Patient will get an additional CT scan consisting of calcium scoring, coronary CT angiography and a stress dual energy scan, and, if radiation dose allows, a late enhancement scan. The maximum radiation dose for the patient will not exceed 10 mSv, based on estimations from literature based on second generation dual source CT (four times the background radiation in the Netherlands). In this study we will use third generation dual source CT so radiation doses will probably be lower but in any case not exceed 10 mSv with even more advanced dose reduction strategies.

The iodine contrast agent used, Iomeron 350® in CT is considered to be very safe and has been used in clinical practice for over a decade.

Adenosine infusion is used in stress perfusion imaging and causes vasodilatation of the coronary arteries. Adenosine is generally well tolerated and is used in daily clinical practice, for instance in SPECT and MR perfusion imaging. In case of a heart rhythm > 65 bpm, beta blocker will be administered. Patient with contraindications to any of the injected agents will not be eligible for participation in this study.

## Contacts

### Public

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## Trial sites

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### 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/m<sup>2</sup>, prosthetic heart valve

- Previously documented myocardial infarction/PCI/CABG

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Will not start

Enrollment: 50

Type: Anticipated

## Ethics review

Approved WMO

Date: 22-08-2016

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## 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

CCMO

Other

### ID

NL53631.042.15

NTR 23951