

# Safety and cost-efficiency of new imaging techniques in addition to cardiac CT-scan in patients with possible coronary artery disease

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON20004

### Source

NTR

### Brief title

iCORONARY - registry

### Health condition

Coronary artery disease

## Sponsors and support

**Primary sponsor:** St. Antonius Hospital

**Source(s) of monetary or material Support:** ZonMW doelmatigheidssubsidie

## Intervention

## Outcome measures

### Primary outcome

The primary objective of the registry is the event rate of MACE and all-cause mortality in a 12

month follow-up period

## **Secondary outcome**

Quality of life

# **Study description**

## **Background summary**

Only small proportion of the 180 000 patients that are referred to a cardiologist each year in the Netherlands with complaints of angina pectoris or shortness of breath suffer from coronary stenosis in such a degree that revascularisation is required. To identify these patients, multiple diagnostic tests are available. Simple non-interventional imaging tests, such as coronary CT-scan, are safe, relatively cheap and can effectively rule-out coronary artery disease. However, when coronary artery disease is present, coronary CT-scan cannot assess the restriction in blood flow caused by the stenosis.

If coronary CT-scan shows no or mild non-flow restricting coronary artery disease, further diagnostic testing is not necessary. In this registry-part of the iCORONARY trial, these patients are included in a registry in which we will assess outcomes and quality of life at various timepoints until 12 months after undergoing CCTA using questionnaires. Following these patients up ensures we obtain a 'real-world' estimate of the ability of CCTA to adequately triage patients with no or low CAD disease burden from patients with intermediate to severe CAD disease burden as practiced in the Netherlands. In other words, it provides us with an estimate of the ability of CCTA to effectively rule out CAD in need of further evaluation.

The primary objective of the registry is the event rate of MACE: all-cause mortality, aborted sudden cardiac death, myocardial infarction and unplanned hospitalization for chest pain leading to urgent revascularization. We hypothesize that the MACE and mortality rates will be very low, due to mild or absent coronary disease on the CCTA and the short follow-up duration.

This study consists of a randomized controlled trial and a patient registry. This is the registration of the patient registry. For the registration of the randomized controlled trial, see registration NL9492

## **Study objective**

We hypothesize that the MACE and mortality rates will be very low, due to mild or absent coronary disease on the CCTA and the short follow-up duration.

## **Study design**

- Week -2: screening and approaching of possible subjects (after referral for coronary CT-scan)
- Week -1: informing possible subject about study procedure (day of coronary CT-scan)
- Week 0: inclusion, informed consent, first (baseline) questionnaire
- 1 month: second questionnaire
- 3 months: third questionnaire
- 6 months: fourth questionnaire
- 12 months: fifth questionnaire

## Contacts

### Public

St. Antonius Hospital  
Leonie Becker

+31 (0)88 320 0900

### Scientific

St. Antonius Hospital  
Leonie Becker

+31 (0)88 320 0900

## Eligibility criteria

### Inclusion criteria

- The subject is  $\geq 18$  years of age
- The subject is willing and able to provide informed consent and adhere to study rules and regulations and follow-up
- The subject has the clinical suspicion of having (recurrent) angina pectoris or an equivalent and suspected coronary artery disease, based on symptoms and signs, history, clinical examination and baseline diagnostic testing (e.g. ECG recording and laboratory tests) as described in the 2019 ESC guideline on chronic coronary syndromes.
- The subject has undergone  $\geq 64$  multidetector row coronary CTA as part of usual care deemed by the treating physician, which shows a CAD-RADS score of 0-2

### Exclusion criteria

- The subject is suffering from unstable angina pectoris.
- The subject is suffering from decompensated congestive cardiac failure.

- The subject is suffering from a known non-ischemic cardiomyopathy.
- The subject has a history of PCI or coronary artery bypass grafting (CABG).
- The subject has had pacemaker or internal defibrillator leads implanted.
- The subject has a prosthetic heart valve.
- There is a severe language barrier.
- The subject participates in any other clinical trial that interferes with the current study.
- Clinical condition prohibiting subsequent interventional therapy as indicated by the results of the imaging procedures.
- The subject is or might be pregnant.
- The subject does not comply or is not able to comply to the imaging guidelines for the performance and acquisition of CCTA by the Society of Cardiac Computed Tomography (SCCT), including:
  - The subject is suffering from a cardiac rhythm other than sinus rhythm.
  - The subject is morbidly obese (Body Mass Index (BMI) > 40).
  - The subject is not able to sustain a breath-hold for 25 seconds.
  - The subject is unable to remain in supine position for at least 30 minutes.
  - The subject has known allergies to or contra-indications to receiving an iodinated contrast agent. Contraindications to receiving an iodinated contrast agent: Glomerular Filtration Rate (GFR) < 45 ml/min/1,73m<sup>2</sup> and if the subject is diabetic or has at least two risk factors for developing contrast induced renal failure a GFR < 60 ml/min/1,73m<sup>2</sup>.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	14-06-2021
Enrollment:	2475
Type:	Anticipated

## IPD sharing statement

**Plan to share IPD:** Yes

## Ethics review

Positive opinion

Date: 26-05-2021

Application type: First submission

## 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	NL9495
Other	MEC-U : R21.026

## Study results