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

Gepubliceerd: 26-05-2021 Laatst bijgewerkt: 18-08-2022

We expect that the total number of invasive cardiac angiography with additional blood flow measurements can be reduced by half with the use of new imaging techniques. We expect that this will lead to a reduction in healthcare costs, complications...

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON25170

**Bron**
NTR

**Verkorte titel**
iCORONARY - RCT

**Aandoening**

Coronary artery disease

### Ondersteuning

**Primaire sponsor:** St. Antonius Hospital
**Overige ondersteuning:** ZonMW Doelmatigheidssubsidie

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

The number of major adverse cardiovasculare events (MACE) - all-cause mortality, aborted sudden cardiac death, myocardial infarction and unplanned hospitalization for chest pain leading to urgent revascularization - in a 12 month follow-up period

# Toelichting onderzoek

### Achtergrond van het onderzoek

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. Cardiac angiography with invasive blood flow measurements is required to assess this restriction in blood flow. This is an invasive test, more expensive than CT and it is accompanied by certain risks.

In retrospect, many patients unnecessarily undergo cardiac angiography with, if needed flow measurements. They do not need treatment for their coronary artery disease. To reduce the number of unnecessary cardiac angiography with flow measurements, new imaging techniques have been developed. These techniques use CT- or angiographic images to calculate the restriction in coronary blood flow and determine the need for treatment. These new imaging techniques have been tested extensively in observational studies. Currently, there is no consensus in the optimal diagnostic pathway resulting in major differences in strategies between hospitals. Moreover,data on cost-effectiveness is lacking.

This study is designed to assess the safety and efficacy of these techniques when used as an addition to coronary CT-scan. Our target population will be patients with complaints of angina pectoris or shortness of breath for which they will undergo coronary CT-scan. If this CT-scan shows no signs of important coronary artery disease, further diagnostic testing is not needed. These patients will be included and followed in a patient registry and are requested to complete 5 questionnaires in a 12-month follow-up period.

If the CT-scan shows one or more possibly flow-limiting stenoses, further diagnostic testing is required. These patients will be randomized in one of three possible arms. One arm will receive additional CT-derived calculation of coronary blood flow, one arm will receive angiography-derived calculation of coronary blood flow and one arm will receive standard routine care. Standard care consists of coronary angiography and invasive coronary blood flow measurements. The results of these tests determine the need for treatment of coronary

artery disease. After these tests, patients will be treated and followed according to routine care guidelines. Similar to the registry, patients will be followed and requested to complete 5 questionnaires in a 12 month follow-up period. The primary endpoint is a composite of MACE – all-cause mortality, aborted sudden cardiac death, myocardial infarction and unplanned hospitalization for chest pain leading to urgent revascularization in a 12 month follow-up period. Secondary endpoints consist of diagnostic performance, hospitalization for unstable angina or other cardiac causes as well as cost-effectiveness. Patient files of their treating physician(s) and the completed questionnaires will be used to collect events during the follow-up period until the last included patient has completed their final questionnaire.

We expect that the total number of invasive cardiac angiography with additional blood flow measurements can be reduced by half with the use of new imaging techniques. We expect that this will lead to a reduction in healthcare costs, complications and a lower burden of diagnostic tests for patients. We do not expect a difference in primary endpoints between the study groups.

This study consists of a randomized controlled trial and a patient registry. This is the registration of the randomized trial. For the registration of the patient registry, see registration NL9495

## Doel van het onderzoek

We expect that the total number of invasive cardiac angiography with additional blood flow measurements can be reduced by half with the use of new imaging techniques.
We expect that this will lead to a reduction in healthcare costs, complications and a lower burden of diagnostic tests for patients.
We do not expect a difference in MACE-events between the study groups.

## Onderzoeksopzet

- 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, randomisation, first (baseline) questionnaire
- Week 1-6: allocated diagnostic test
- 1 month: second questionnaire
- 3 months: third questionnaire
- 6 months: fourth questionnaire
- 12 months: fifth questionnaire

## Onderzoeksproduct en/of interventie

- CT-derived FFR: CT-images will be processed by an algorithm to calculate FFR-values of the full coronary tree
- Angiography-derived FFR: FFR-values are calculated during coronary angiography based on the acquired images of the coronary arteries
- Angiography with invasive FFR-measurements: during coronary angiography, a specialized

pressure wire is passed through the coronary stenosis to calculate FFR based on the difference between the actual pressure and the expected pressure in the hypothetical healthy coronary artery.

# Contactpersonen

## Publiek

St. Antonius Hospital
Leonie Becker

+31 (0)88 320 0900

## Wetenschappelijk

St. Antonius Hospital
Leonie Becker

+31 (0)88 320 0900

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- The subject is ≥ 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 had ≥64 multidetector row coronary CTA as part of usual care deemed by the treating physician which shows possibly significant coronary artery disease with a CAD-RADS >2

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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/1,73m2 and if the subject is diabetic or has at least two risk factors for developing contrast induced renal failure a GFR < 60 ml/min/1,73m2.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 14-06-2021 |
| Aantal proefpersonen: | 825 |
| Type: | Verwachte startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Ja

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 26-05-2021 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL9492 |
| Ander register | MEC-U : R21.026 |

## Resultaten