Replacement of invasive diagnostic coronary procedures by innovative noninvasive Imaging Technologies

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22758

Source
NTR

Brief title
REPLACE-it

Health condition

Coronary Artery Disease
Cardiac ischemia
Magnetic Resonance Imaging
Cardiac computed tomography
CTA
MRI

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Zon-MW IMDI (Innovative Medical Device Initiative Netherlands)
Siemens

Intervention

Outcome measures

Primary outcome

The primary endpoint is the performance of noninvasive imaging (combined CTA and MR perfusion) to diagnose flow-limiting CAD compared to the reference standard of ICA.

Secondary outcome

Secondary endpoints include the performance of individual components of the noninvasive imaging approach, the ability to guide revascularization strategy and the prediction of improvement of perfusion after revascularization.

Study description

Background summary

Coronary Artery Disease (CAD) is expected to remain the leading cause of death for the next 20 years, posing a major burden on society. A considerable proportion of costs related to the management of (suspected) CAD are due to Invasive Coronary Angiography (ICA), which is indicated in high-risk patients and in patients with noninvasive testing suggestive of significant CAD. Noninvasive imaging techniques show promising potential to replace a large proportion of the current practice of ICA. The REPLACE-IT study is a prospective single-centre observational study with the aim to establish a noninvasive, quantitative imaging approach to (1.) determine if flow or perfusion-limiting CAD is present, (2.) guide the indication for percutaneous intervention or bypass grafting, and (3.) predict the hemodynamic improvement after revascularization. Non-acute, symptomatic patients scheduled to undergo elective ICA are eligible for this study. In total 440 men and women (aiming to include equal numbers by gender) will be recruited from the cardiology outpatient clinic at the UMCG, where we see approximately 2500 eligible patients annually. Patients will undergo a diagnostic algorithm consisting of coronary (Computed Tomography Angiogram) CTA and myocardialMagnetic Resonance (MR) perfusion before ICA. A second MR perfusion will be performed only when the patient received a coronary intervention. The primary endpoint is the comparison of noninvasive imaging (combined CTA and MR perfusion) to diagnose flow limiting CAD with reference standard of ICA+/-FFR. Secondary endpoints include the performance of individual components of the noninvasive imaging approach, the ability to guide revascularization strategy and the prediction of improvement of perfusion after revascularization. We expect to establish a noninvasive imaging approach to reduce the number of ICA.

Study objective

The hypothesis is that non invasive imaging techniques (CTA + stress MR perfusion) are a

suitable replacement for diagnostic Invasive Coronary Angiography (ICA) in the diagnosis of Coronary Artery Disease.

Study design

01-11-18: Start inclusion

01-12-19: 100 patients included

01-12-21: 400 patients included

01-06-22: Final results

Intervention

Before ICA patients will undergo both CT Coronary Angiography (CTA) and adenosine MR perfusion imaging. In case of significant CAD during ICA, a second MR perfusion scan after the intervention will

Contacts

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Eligibility criteria

Inclusion criteria

All patients >18 years of age referred for ICA as part of standard clinical care for evaluation of suspected CAD

Exclusion criteria

Major exclusion criteria are:

- Unable to provide written informed consent

- ICA planned for other reasons than suspected obstructive CAD (e.g. screening prior to lung transplantation, valvular surgery, or ICD implantation)

- Significant arrhythmia deemed to interfere with successful ECG triggered non-invasive imaging as judged by a cardiologist.

- Renal insufficiency: GFR <50ml/min

- Known anaphylactic allergy to iodine

- Known severe comorbidities with a life expectancy of less than 1 year

- Known severe claustrophobia

- Known contra-indications for beta-blocker or adenosine

- Instable coronary artery disease (acute coronary syndrome or instable angina)

- Other contraindications for CTA or MR perfusion (e.g. presence of incompatible pacemaker or ICD devices/leads, pregnancy, BMI >35 kg/m2).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2018

Enrollment:	440
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-09-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47060
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5897
NTR-old	NTR6085
CCMO	NL57105.042.16
OMON	NL-OMON47060

Study results