Addition of FFRct in the diagnostic pathway of patients with stable chest pain to reduce unnecessary invasive coronary angiography

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To assess the impact of adding FFRct analysis to CCTA on the rate of unnecessary invasive coronary angiography (ICA) in patients with stable chest pain that have a >=50% but less than 90% anatomical stenosis on CCTA in any major epicardial vessel...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON54357

Source
ToetsingOnline

Brief title
FUSION Study

Condition

- Coronary artery disorders

Synonym
major epicardial vessel stenosis ; chest pain

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W,Heartflow

Intervention

Keyword: coronary angiography, FFRct, major epicardial vessel stenosis, stable chest pain

Outcome measures

Primary outcome

The primary endpoint is the percentage of unnecessary ICA at 90 days.

Unnecessary ICA is defined as an ICA without hemodynamically significant coronary artery disease (CAD).

ICA with no hemodynamically significant CAD is defined as no invasive FFR <= 0.80 or no iFR <= 0.89 in a coronary artery >= 2 mm;

or if FFR or iFR is not performed, no >= 50% stenosis on the quantitative coronary angiography (QCA) in a coronary >= 2 mm; or if QCA is also not available, no visual stenosis of >= 70% or in the case of the main stem no stenosis of >=50% in a coronary artery >= 2 mm.

Secondary outcome

• Percentage of unnecessary ICA after 1 year

The following endpoints are determined after 90 days and after 1 year:

• Serious Adverse Cardiac Events (MACE), including all-cause mortality, non-fatal myocardial infarction (MI), and unplanned hospitalization leading to urgent revascularization

• Cost-effectiveness analysis and budget impact analysis

• Number of additional non-invasive tests for CAD assessment

• All coronary revascularizations (planned / unplanned)

•Quality of life

• Cardiovascular mortality

• Complications after ICA

• Non-fatal stroke

Study description

Background summary

Patients with stable chest pain enter a diagnostic pathway where Coronary Computed Tomography Angiography (CCTA) is often the first line non-invasive test to detect coronary stenosis. An anatomically significant (>= 50% luminal narrowing) stenosis on CCTA does however not always cause cardiac ischemia (i.e. hemodynamically significant stenosis).

CCTA is often followed by invasive coronary angiography (ICA) to assess the hemodynamic significance of the stenosis which is the key determinant to decide on treatment (revascularization by coronary stenting or surgery).
CCTA has a very high negative predictive value but the positive predictive value is moderate. Hence, anatomically significant stenoses on CCTA often turn out not to be hemodynamically significant on ICA.
Fractional Flow Reserve from coronary computed tomography (FFRct) analysis is a new non-invasive technique that uses the CCTA images as a basis for complex software based calculations and modelling to provide additional functional information based on the anatomical CCTA images. Thus,

FFRct is a totally non-invasive method. Adding the FFRct analysis to the anatomical assessment of CCTA is expected to reduce the number of patients being referred to ICA where no signs of hemodynamically significant stenosis are found on ICA.

Study objective

To assess the impact of adding FFRct analysis to CCTA on the rate of unnecessary invasive coronary angiography (ICA) in patients with stable chest pain that have a >=50% but less than 90% anatomical stenosis on CCTA in any

major epicardial vessel with a diameter of >= 2 mm.

Study design

Randomised controlled trial (RCT) and combined post-hoc analysis in control group.

Study burden and risks

The patient burden to participate is negligible since CCTA data that were already acquired will be used for additional analysis.

The FFRct functional analysis of CCTA images does not require extra site visits. To assess QOL, participating patients will have to fill in 3 questionnaires at baseline, at 90 days and at 1 year.
Additionally, patients fill in a questionnaire as an addition to the case record form to be certain no events during follow-up were missed.
Clinical follow-up will be collected at 90 days and 1 year by a visit to the outpatient clinic and/or by telephone call.

The risks of false negative FFRct resulting in cardiac events is extremely low and therefore in our view acceptable. The data available from literature shows the per patient sensitivity of FFRct to be very high (up to 96%) and false negative ratio to be very low (4%). In patients with a negative FFRct result (>0.80) the rate of MACE during follow-up is extremely low.

A patient may benefit from participation, as it is expected that a part of the intervention group will not need invasive diagnostics.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >= 18 years
- Stable chest pain and the patient underwent CCTA which demonstrated >=*50% but less than 90% stenosis in any major epicardial vessel with a diameter >= 2 mm.

Exclusion criteria

- Inability to provide informed consent
- Unstable angina according to ESC guidelines
- Unstable clinical status
- Expected inability to complete follow-up and comply with follow-up aspects of the protocol
- History of coronary revascularisation
- Non-invasive or invasive diagnostic testing for CAD within the past 12 months (with the exception of exercise ECG)
- Unsuitable for revascularisation if required (for example due to comorbidities or anatomical features)
- Poor CT quality with expected inability to perform FFRct analysis

Study design

Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-07-2021
Enrollment:	528
Type:	Actual

Medical products/devices used

Generic name:	Heamodynamic modelling web-based application software
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-07-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-10-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-04-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-03-2023

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-06-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-05-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-02-2025
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL76830.078.21