The iCORONARY Caristo biomarker study

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

Summary

ID

NL-OMON56410

Source
ToetsingOnline

Brief title
iCORONARY-Caristo/Biomarker

Condition

- Coronary artery disorders

Synonym
Coronary artery disease, coronary artery stenoses

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Bedrijf,Roche

Intervention

Keyword: Biomarkers, Coronary artery disease, Coronary CTA, Pericoronary inflammation

Outcome measures

Primary outcome

The primary objective of this study is to investigate:

• The difference after 1 year with and without cardiovascular risk modification:

o in CaRi Heart Score

o in Biomarker-levels

o in traditional CT-parameters such as calcium score and CAD RADS score

Secondary outcome

this study also addresses the secondary objectives below:

• Correlation between CaRi Heart Score, QRISK 3 score, ESC SCORE2 and biomarker levels at baseline and after 1 year

• Ability of CaRi Heart score to predict major adverse cardiac events and CAD progression

• Added value of biomarker-levels to CaRi Heart score event prediction

Study description

Background summary

For personalized risk modification there is need for a parameter which reliably estimates an individual's risk for cardiovascular events in the future, and allows for monitoring of risk modification effectiveness. CaRi Heart score measures pericoronary inflammation on routine coronary CT, shows this as percentile for sex and age and used this and traditional risk factors to calculate the CaRI Risk score, an individual's risk for a (fatal if left untreated) cardiovascular event in the next 8 years. We expect that this will allow us to more adequately tailor cardiovascular risk modification to an individual's risk. Additionally, we expect that with adequate risk modification the pericoronary inflammation will decrease, which means the effectiveness of

cardiovascular risk modification could be monitored and management strategy can be adapted.

Additionally, various biomarkers have been identified that are associated with an elevated risk of coronary artery disease. However, their precise clinical value remains unknown, among others due to limited validation opportunities. We want to assess whether these biomarkers can be validated using pericoronary inflammation, and whether they have potential additional value in risk prediction when combined with the CaRi risk score.

Study objective

We aim to assess whether risk modification effectiveness is visible on follow-up CT and in biomarker values when comparing baseline with 12 months follow-up in patients without significant obstructive coronary artery disease on coronary Ct. We also aim to assess whether the biomarkers correlate with pericoronary inflammation, whether they have added value compared to CaRi score alone and whether CaRi score and biomarker values can be used to develop a treatment strategy for prevention tailored to the individual patient

Study design

This prospective observational study applies to the original study design of the iCORONARY trial, a multicenter, randomized controlled trial. All study patients involved in the registry arm of the main study and included from the sponsor center can opt-in and opt-out to participate in this study.

Study burden and risks

Acquisition of a CCTA delivers an effective dose of approximately 5mSv of radiation. Normal background radiation is approximately 3mSv per year. For this study, patients receive 2 CCTAs within a 12 month period. The risk of a negative health impact with this radiation dose is low. We will however advise patients to not participate in other studies involving radiation simultaneously with this study and will not include patients that have recently received or are planned to receive other diagnostic tests involving radiation. Iodine contrast is needed for CCTA. Contra-indications for iodine contrast are impaired kidney function (GFR <30ml/min or GFR<45ml/min in high risk patients) and contrast allergies. We will not include patients with contra-indications for iodine contrast in this study. Because the experimental results from biomarker levels and CaRi Risk assessment will not be used in clinical management, potential false-negative or false positive results do not carry any risk for the patient. * Patients will be informed of the possibility of chance findings with blood test or CCTA that might be relevant to their health and call for additional treatment or diagnostic testing. If this occurs, patients will be referred to their cardiologist, an different medical specialist or

their general practitioner depending on the findings.

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

All potential participants will be derived from the ICORONARY registry, meaning iCORONARY inclusion criteria apply, These can be found in the protocol, paragraph 4 section 2: inclusion criteria.

Additional inclusion criteria that apply to participants in this study are:
• The subject is between 30 and 80 years of age
• The subject is included in the iCORONARY registry by researchers in the St. Antonius Hospital
• The subject has no anatomically significant coronary artery disease on index

CCTA (CADRADS 0-2)

Exclusion criteria

All potential participants will be derived from the ICORONARY registry, meaning iCORONARY exclusion criteria apply, These can be found in the protocol, paragraph 4 section 3: exclusion criteria.

In addition to all iCORONARY-exclusion criteria (as inclusion for iCORONARY registry indicates that none of these exclusion criteria are met)
• The subject is suffering from chronic inflammatory diseases or (auto)immune disorders
• The subject is suffering from an active malignancies and/or currently receives treatment for a malignancy
• The subject is currently receiving oral, systemic or long-term cutaneous steroid therapy, or any other oral or systemic immune-suppressive medications.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2023
Enrollment:	400
Type:	Anticipated

Medical products/devices used

Generic name:	CaRi Risk Score
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-12-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL84785.100.23