INSIDE-LRP: Non-Invasive Identification with Computed Tomography Coronary Angiography of Vulnerable Lipid-Rich Plaques

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To develop a non-invasive algorithm that allows the detection of LRPs with CTCA

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

Summary

ID

NL-OMON51163

Source
ToetsingOnline

Brief title
INSIDE-LRP

Condition

- Coronary artery disorders

Synonym
coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,B.Braun Melsungen AG,Infraredx, A Nipro Company

Intervention

Keyword: Computed tomography coronary angiography, Intravascular ultrasound, Near-infrared spectroscopy

Outcome measures

Primary outcome

The ability of CTCA to detect a LRP (LCBImm4 > 400) as identified by NIRS

Secondary outcome

o The CTCA plaque characteristics of lipid-rich plaques (i.e. plaques with

LCBImm4 >400), as identified with NIRS.

o The CTCA characteristics of near-lipid-rich coronary plaques with LCBImm4 of

*250 and <400.

o To correlate the CTCA findings and IVUS findings of lipid-rich plaques

(LCBImm4 >400) and near-lipid-rich plaques (LCBImm4 between 250 and 400).

Study description

Background summary

Two-thirds of intracoronary thrombi causing acute coronary syndrome (ACS) result from rupture of lipid-rich plaques (LRP). Near infrared spectroscopy (NIRS) combined with intracoronary ultrasound (IVUS) can identify these vulnerable plaques during coronary angiography (CAG) and is able to assess plaque characteristics and the lipid-core burden index in a 4mm segment (LCBImm4). Computed tomography coronary angiography (CTCA) may be an alternative, non-invasive method to detect vulnerable plaques. This additional imaging technique, combined with artificial intelligence-based analysis, could contribute to earlier detection of LRPs, generating insight into the underlying pathogenesis.

Study objective

To develop a non-invasive algorithm that allows the detection of LRPs with CTCA

Study design

Observational study

Study burden and risks

Patients will undergo additional 3-vessel IVUS-NIRS imaging, leading to an additional extra 3 minutes in the cathlab, with a maximum of 1 minute extra radiation and a maximum of 15 cc extra contrast.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Subject underwent computed tomography coronary angiography within the previous two months;
2. Subject is scheduled for subsequent invasive coronary angiography.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1. Acute coronary syndrome with ST-segment elevation;
2. Acute coronary syndrome without ST-segment elevation with hemodynamic instability or ongoing ischemia, requiring urgent revascularization;
3. Estimated glomerular filtration rate <30 ml/min/1.73 m2;
4. Contrast allergy;
5. Subject is pregnant or breastfeeding.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-07-2021
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Near-infrared spectroscopy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL76046.018.20