Clinical outcomes and cost-effectiveness of a diagnostic and treatment strategy of upfront CTCA plus selective non-invasive functional imaging compared with standard care in patients with chest pain and suspected coronary artery disease

Published: 01-08-2022
Last updated: 24-05-2024

This strategy will result in a reduction reduce the incidence of major adverse cardiovascular events (MACE) defined as death or non-fatal myocardial infarction and appear more efficient than care as usual.

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

Summary

ID

NL-OMON56132

Source
ToetsingOnline

Brief title
CLEAR-CAD

Condition

- Coronary artery disorders

Synonym
chest pain; coronary artery disease

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Chest pain, Coronary artery disease, CTCA

Outcome measures

Primary outcome

1. Occurrence of MACE defined as mortality or non-fatal myocardial infarction

2. Costs per quality adjusted life year (QALY)

Secondary outcome

Please see page 10 of the research protocol (Chapter 2.2: Secondary objectives)

Study description

Background summary

What is the clinical effect and cost-effectiveness of a combined diagnostic and treatment strategy in patients with suspected coronary artery disease (CAD)? This strategy comprises of upfront computed tomography coronary angiography (CTCA) with selective non-invasive functional imaging and patient tailored therapy.

Study objective

This strategy will result in a reduction reduce the incidence of major adverse cardiovascular events (MACE) defined as death or non-fatal myocardial infarction and appear more efficient than care as usual.

Study design

Randomized controlled trial (RCT)

Intervention

Upfront CTCA with standardized reporting through CAD-RADS classification. CAD-RADS 0 rules-out CAD. CAD-RADS 1 & 2 rules-out obstructive CAD with high certainty and optimal preventive drug therapy (OMT) is then initiated. In patients CAD-RADS =3, obstructive CAD is assumed and OMT will be started with additional anti-anginal medication (OMT +). In this latter group, additional non-invasive functional imaging will be performed if anginal complaints persist under OMT +. Patients with> 10% myocardial ischemia on imaging will undergo revascularization in consultation with the cardiac team.

Study burden and risks

Please see page 25 of the research protocol (Chapter 11.3: Benefits and risks assessment, group relatedness)

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

Outpatient presentation to the cardiologist with chest pain with suspected CAD
- >18 years old

Exclusion criteria

Patients who meet any of the following criteria will be excluded from participation:
- Presentation with acute coronary syndrome (NSTEMI/STEMI/unstable angina)
- Acute coronary syndrome (including unstable angina) within past 3 months
- History of obstructive coronary artery disease on imaging (>50% DS)
- History of PCI and / or CABG
- Severe renal failure (eGFR <30 ml/min)
- Severe allergy to iodinated contrast medium
- Known pregnancy
- Patients with an estimated life expectancy of less than 1 year

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-09-2022
Enrollment:	6444
Type:	Actual

Ethics review

Approved WMO Date:	01-08-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-08-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-11-2022
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	17-01-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	21-06-2023

Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Approved WMO Date:	12-09-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Approved WMO Date:	12-10-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Approved WMO

Date:	31-01-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Approved WMO Date:	15-02-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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
ClinicalTrials.gov	NCT05344612
CCMO	NL81264.018.22