Coronary calcium scoring as first-line test to detect and exclude coronary artery disease in GP patients with stable chest pain

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29084

Source
Nationaal Trial Register

Brief title
CONCRETE

Health condition

coronary artery disease
diagnosis
general practitioner

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Hartstichting (Dutch Heart Foundation)

Intervention

Outcome measures

Primary outcome

To determine the increase in detection / treatment rate of CAD in GP offices with the calcium score-based strategy, compared to GP offices with the routine care strategy, as measured by number of patients registered for/treated by the CardioVascular Risk factor Management guideline.

Secondary outcome

Secondary outcomes include individual-based outcomes such as effectiveness of CAD diagnosis and referral, and the effect of CT calcium scoring on reduction of MACE

Study description

Background summary

CONCRETE is an implementation study, focused on the Dutch health care system. In the Netherlands, the General Practitioner (GP) is the first physician a patient consults with non-acute chest discomfort. In the Dutch GP Guideline (NHG-Standaard) for stable chest pain complaints, referral to the cardiologist is recommended for (a)typical angina pectoris (AP), and only when CAD is suspected, in non-specific thoracic complaints. In outpatient cardiology clinics, the calcium score, based on a low dose computed tomography (CT) scan, has been found to have high accuracy for diagnosis and exclusion of CAD. The CT-calcium score has the added potential advantage of being able to detect early stages of CAD. At this moment, it is still unclear what the best strategy is for atypical AP and non-specific thoracic complaints in GP setting. The standard of care and CT calcium scoring can be considered competitive tests, for which medical experts/researchers differ in opinion regarding the best diagnostic strategy as first line test for CAD in atypical chest pain and non-specific thoracic complaints with suspicion of CAD. In addition, CT calcium scoring also detects subclinical CAD. It is possible that treatment of subclinical CAD may prevent myocardial infarction or sudden cardiac death in the future due to early treatment, although at this moment this is still unclear.

CONCRETE is an implementation study of CT calcium scoring in GP setting. The design is a pragmatic cluster randomized trial in which direct access to CT calcium scoring is compared to standard of care in patients with chest discomfort. Randomization will take place at GP office level. The primary units of randomization are 80 GPs, who will be randomized (1:1) to a strategy. For secondary analyses, we aim to obtain informed consent of the approximately 1600 subjects.

CONCRETE aims to: (1) evaluate whether GP access to CT calcium scoring leads to earlier CAD diagnosis and treatment, (2) assess and optimize gender-specific diagnostic stratification based on the calcium score, (3) determine which (cluster of) symptoms and risk factors could assist in web-based self-assessment of CAD, and (4) translate study findings to

initiate a change in Dutch health care policy by providing data on cost-effectiveness.

Study objective

CONCRETE aims to evaluate whether GP access to CT calcium scoring leads to earlier CAD diagnosis and treatment.

Study design

The increase in early diagnosis of CAD will be determined by performing a baseline measurement and a follow-up assessment after 2
years at the participating practices.

Intervention

The design is a pragmatic cluster randomized trial in which direct access to CT calcium scoring is compared to routine care in patients with chest discomfort. Randomization will take place at GP level.

Patients in both clusters will be asked for consent to fill in questionnaires and for the researchers to gather data on work-up and follow-up.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with non-acute chest discomfort, either atypical AP or aspecific chest pain, with indication for further diagnostic testing as determined by the GP

Exclusion criteria

Men under 40 years, women under 45 years

Pregnancy

Unwilling to provide written informed consent for the individual level outcomes

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-12-2017
Enrollment:	1600
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
After the main results of the trial have been published, data requests can be performed for specific data of the study; precise criteria for data access will be determined at a later stage.

Ethics review

Positive opinion

Date:	10-01-2019
Application type:	First submission

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
NTR-new	NL7475
NTR-old	NTR7717
Other	201800435 : UMCG research register

Study results

Summary results

https://www.hartstichting.nl/wetenschappelijk-onderzoek/slagaderverkalking/sneller-zekerheid-over-je-hart