Reviving Early Diagnosis of CardioVascular Disease

Published: 09-10-2018
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Objective of this study is to compare the diagnostic yield of the Early Diagnosis Strategy to usual care, in terms of detection and subsequent treatment of previously unrecognized CAD, AF and HF.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON52511

Source
ToetsingOnline

Brief title
RED-CVD

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
Cardiovascular disease, coronary artery disease and heart failure), heart disease (atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Hartstichting

Intervention

Keyword: Cardiovascular disease, COPD, Diabetes, Early diagnosis

Outcome measures

Primary outcome

The number of newly detected cases with CVDs (heart failure, atrial fibrillation or coronary artery disease) in both arms, and the subsequent targeted therapies these new cases received.

Secondary outcome

1. the added diagnostic value of family history taking, and, in women, reproductive history

2. the added diagnostic value of biomarkers other than NT-proBNP, i.e. high-sensitive troponine (hs-Tn), growth differentiation factor 15 (GDF-15),ST-2?

3. the cost-effectiveness of the Early Diagnosis Strategy compared to usual care

Study description

Background summary

The early stages of cardiovascular disease (CVD) generally cause non-specific or atypical symptoms that patients often do not spontaneously mention to their general practitioner. This makes that new onset CVD is easily missed. A more proactive diagnostic strategy has the potential to uncover these frequently missed early stages, thus creating an opportunity for early intervention that may prevent progression into chronic CVD or devastating acute cardiovascular events. This is of particular importance for cardiovascular diseases with evidence-based therapies known to improve prognosis, such as coronary artery disease (CAD), atrial fibrillation (AF) and heart failure (HF).

Previous studies have shown that patients with type 2 diabetes (T2D) or chronic obstructive lung disease (COPD) are at highly increased risk of developing CVD, and that 20-65% of these patients have 'concealed' CVD. In the current study, we will test a newly developed Early Diagnostic Strategy, aimed at these high risk patients and blended in with the primary care disease management programs these patients routinely participate in.

Study objective

Objective of this study is to compare the diagnostic yield of the Early Diagnosis Strategy to usual care, in terms of detection and subsequent treatment of previously unrecognized CAD, AF and HF.

Study design

A cluster randomized diagnostic trial with 40 primary care practices at the unit of randomization.

Intervention

The two stage Early Diagnostic Strategy, consisting of the Early Diagnosis Questionnaire (stage 1) to be filled in at home prior to the next routine visit, followed if necessary by physical examination of legs, heart and lungs, electrocardiography and BNP-measurement (stage 2).

Study burden and risks

As our new Early Diagnosis Strategy is to be blended in with the well-established primary care disease-management programs for COPD and T2D, the burden associated with participation will be relatively low. No extra visits will be required; patients will be asked to fill out the questionnaires before their regular visits. Our strategy depends solely on non-invasive and minimally invasive (blood taking), standard diagnostic procedures. In case of suspected CVD, standard diagnostic procedures will be applied according to (inter)national guidelines on CVDs. There is a potential benefit associated with participation, as we aim to uncover early stage CVD that might not have been detected otherwise, and for which early treatment is prognostically beneficial. Minors and persons with severe cognitive impairment or who are not proficient in Dutch will not be included.

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

1. Currently enrolled in a primary care (chronic) disease management program for either COPD or T2D
2. Age 18 years or over
3. Willing to sign informed consent

Exclusion criteria

1. Not proficient in Dutch or having severe cognitive impairment (i.e. not able to understand and correctly fill in the questionnaire)
2. Having a triple diagnosis of HF, CAD and AF. Confirmed with echocardiography in case of HF, with coronary angiography, exercise-test, stress-echo, stress MRI, SPECT-CT/MIBI or calcium score > 100 on CT-scan in case of CAD, with electrocardiography in case of AF.

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2019
Enrollment:	1300
Type:	Actual

Ethics review

Approved WMO Date:	09-10-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	07-06-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-10-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-05-2020
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	10-06-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-02-2022
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24396
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65798.041.18
OMON	NL-OMON24396

Study results

Date completed:	01-03-2023
Actual enrolment:	1278