Early recognition of cardiovascular disease

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24396

Source
NTR

Brief title
RED-CVD

Health condition

Cardiovasculaire ziekten
Hart- en vaatziekten
Atriumfibrilleren
Coronairlijden
Hartfalen
Cardiovascular disease
atrial fibrillation
coronary artery disease
heart failure

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

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 BNP, 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

Rationale: 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. In the current study, we will test a newly developed Early Diagnosis Strategy, aimed at these high risk patients and blended in with the primary care disease management programs these patients routinely participate in.

Objectives: Firstly, 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. Secondly, to demonstrate the added diagnostic value of extensive family and reproductive history taking and that of three (novel) biomarkers. Thirdly, to demonstrate that

the Early Diagnosis Strategy is cost-effective compared to usual care.

Study design: A cluster randomized diagnostic trial will be conducted in 40 primary care practices, including adults who are enrolled in the disease-management programs for COPD or T2D. The main outcome of this study is the number of newly detected cases with CVDs in both arms, and the subsequent targeted therapies these new cases received. The Early Diagnosis Strategy will be blended in with the routine visits that are part of these disease-management programs. The Early Diagnosis Strategy is a two-stage intervention, consisting of a questionnaire which is, in case of positive answers, followed by physical examination, electrocardiography, and N-terminal natriuretic peptide measurement NT-proBNP. In case of findings suggestive of CVD, additional investigations will be performed by the GP or cardiologist after referral, in line with existing guidelines. In addition, questionnaires on detailed family history and, for women, reproductive history will be filled out in the intervention arm and the added diagnostic value to the Early Diagnosis Strategy will be calculated. Furthermore, extra blood samples from all participants in the intervention arm will be drawn during the same venapuncture used for NT-proBNP-measurement, to investigate the diagnostic value of several cardiac biomarkers, i.e. high sensitive troponin I (hs-Tn I) , ST-2 and growth differentiation factor 15 (GDF-15), for the detection of the target CVDs.

Study objective

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 cluster-randomized diagnostic trial, 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.

We hypothesize that the Early Diagnosis Strategy will uncover 10% new cases of CAD, AF or HF in patients with T2D or COPD; an additional 5% to the 5% expected to be detected with usual care.

Study design

At inclusion, all patients will fill out the EQ-5D-5L questionnaire on health-related quality of life. Patients in the control arm will receive care as usual within the primary care disease management program (DMP)for COPD or T2D. Patients in the intervention arm will undergo the Early Diagnosis Strategy. Prior to their next routine visit that will have been scheduled as part of the DMP they participate in, they will be asked to fill out the Early Diagnosis Questionnaire on signs and symptoms suggestive of CVDs. In addition, they will be asked to fill out questionnaires on family history and, for women, reproductive history. During the scheduled routine visit, the GP or practice nurse will review their answers. In case of positive answers, the patient will undergo electrocardiography (ECG), NT-proBNP measurement and a physical examination. And extra vial of blood will be drawn during the same venapuncture used for NT-proBNP measurement and serum samples will be stored in a biobank. In case of elevated NT-proBNP or abnormalities found with ECG or physical examination, the patient will be referred to a cardiologist for further investigations and treatment according to guidelines. One year after the initial routine visit took place, follow-up data (new diagnoses, referrals, medication prescribed, outpatient visits and hospital admissions) will be collected in both arms. The stored serum samples will be thawed and three cardiac biomarkers will be measured (GDF-15, hs-TnI, ST-2).

Intervention

Patients in the intervention arm will undergo the Early Diagnosis Strategy. The Early Diagnosis Strategy consists of a questionnaire that can be filled in online prior to their routine visit to their general practitioner and which, in case of a positive answer to one of the questions, is followed by focused physical examination (inspection of legs and neck and auscultation of heart and lungs), electrocardiography and blood-drawing for BNP-measurement. In patients who undergo blood drawing for BNP-measurement, an extra 10 mL of blood will be drawn during the same venapuncture, and stored in a sub-biobank. Part of this will be used at the end of the study to measure three (novel) cardiac biomarkers. The other part will remain in the biobank for future cardiac biomarker studies. Patients in the intervention arm will also be asked to fill in additional short questionnaires on female-specific history and family-specific history.

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Eligibility criteria

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:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-12-2018
Enrollment:	1300
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 52511
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7161
NTR-old	NTR7360
CCMO	NL65798.041.18
OMON	NL-OMON52511

Study results