Impact of a cardiac rehabilitation program versus coronary revascularization in patients with stable coronary artery disease

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We hypothesise that the PRO-FIT intervention is non-inferior with respect to angina symptoms as compared to a routine invasive approach.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24082

Bron
Nationaal Trial Register

Verkorte titel
PRO-FIT

Aandoening

Stable angina pectoris

Ondersteuning

Primaire sponsor: Maxima Medisch Centrum
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome will be the quantity of angina symptoms (evaluated by the Seattle Angina Questionnaire (SAQ-7)) following the 12-month intervention.

Toelichting onderzoek

Achtergrond van het onderzoek

Stable angina pectoris (SAP) is a highly common condition in the Netherlands. Despite optimal medical treatment patients often remain symptomatic and at risk for cardiovascular morbidity and mortality. In daily practice often an invasive strategy is applied in these patients consisting of coronary angiography and subsequent coronary revascularization by percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). However, in a large recent trial and meta-analysis, this costly and invasive procedure did not show beneficial effects on prognosis in patients with SAP. An important reason for the high disease burden in these patients might be the non-adherence to healthy lifestyle advices. The potential of lifestyle-related interventions on progression of coronary artery disease is well-known but contemporary RCT's comparing cardiac rehabilitation with coronary revascularization are lacking. To optimize the long-term clinical effects and wide-scale implementation, these interventions should have a sound physiological basis, be personalized to a patients' needs and preferences, include effective behavioural change strategies and be easily accessible in the current healthcare system.

This project aims to compare the impact of a 12-month cardiac rehabilitation program (PRO-FIT) vs. an invasive strategy consisting of coronary angiography with subsequent coronary revascularization (usual care) in SAP patients under optimal medical therapy (OMT). PRO-FIT may represent a cheaper and clinically and socioeconomically superior strategy to replace elective coronary revascularization as the principal treatment after OMT. PRO-FIT is designed specifically for patients with SAP and aimed at a decrease in symptoms.

Doel van het onderzoek

We hypothesise that the PRO-FIT intervention is non-inferior with respect to angina symptoms as compared to a routine invasive approach.

Onderzoeksopzet

December 2021: Start enrollment
December 2022: Final enrollment
December 2023: End of follow-up

The intervention lasts one year.
The last follow-up will take place one year after enrollment.

Measurements take place at baseline, and after 3, 6, 9 and 12 months.

Onderzoeksproduct en/of interventie

A 12-month cardiac rehabilitation program (PRO-FIT) aiming at angina relief and sustainable behavioural change for long-lasting improvement in cardiovascular health. PRO-FIT will consist of multiple lifestyle interventions including an exercise program and a dietary intervention with a stepped decline in guidance by health care professionals to encourage the sustainability of behavioural change.

Contactpersonen

Publiek

Radboudumc
Iris de Koning

0657121219

Wetenschappelijk

Radboudumc
Iris de Koning

0657121219

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- A diagnosis of SAP with residual angina symptoms after OMT
- Established ischemia (assessed by SPECT, PET, Stress ultrasound, CMR, or cycle ergometry)
- Access to a personal computer, laptop or tablet with Internet connectivity at home.
- Access to a mobile phone with short message service (SMS) functionality to login to the web application with two-factor authentication.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

An echocardiography and coronary angiography (usual care group) or coronary computed

tomography (CT)-angiography (CR group) will be performed to exclude high-risk patients with a reduced left ventricular function (i.e. left ventricular ejection fraction <35%). After randomisation patients will also be screened for stenosis of the left main coronary artery through computed tomography (intervention group) or coronary angiogram (control group). For these patients previous work revealed the potential prognostic benefit of revascularization, in terms of mortality, also supported by latest guidelines on myocardial revascularization with a class 1A indication for revascularization.

Other exclusion criteria include:
1. PCI or CABG in the past year
2. Acute coronary syndrome in past 2 months
3. Angina symptoms at rest or rapidly progressive (i.e. unstable angina)
4. Ischemic threshold <50 watts
5. New-York Heart Association class III-IV heart failure symptoms
6. Advanced chronic kidney failure (i.e. estimated Glomerular Filtration rate <30ml/min)
7. Severe ventricular arrhythmia or exercise-induced arrythmia at baseline testing
8. A comorbidity precluding exercise training (e.g. orthopaedic, neurological or cognitive conditions) or other contra-indications for exercise training.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2021
Aantal proefpersonen:	216
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52330
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9537
CCMO	NL77210.091.21
OMON	NL-OMON52330

Resultaten