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

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1. To compare the impact of a 12-month cardiac rehabilitation program (PRO-FIT) vs. an invasive approach including coronary angiography and subsequent coronary revascularization in stable angina pectoris patients on angina symptoms.2. To evaluate...

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

Summary

ID

NL-OMON52330

Source
ToetsingOnline

Brief title
PRO-FIT

Condition

- Coronary artery disorders

Synonym
chestpain, Stable angina pectoris

Research involving
Human

Sponsors and support

Primary sponsor: Maxima medisch centrum

Source(s) of monetary or material Support: ZonMw,Astra Zeneca,Novo Nordisk

Intervention

Keyword: Cardiac rehabilitation, Exercise training, Percutaneous coronary intervention, Stable angina pectoris

Outcome measures

Primary outcome

The primary outcome will be the quantity of angina symptoms (evaluated by the

SAQ-7) following the 12-month intervention.

Secondary outcome

Secondary outcomes include cost-effectiveness, the ischemic threshold during

exercise, cardiovascular events, quality of life, fitness, cardiovascular

health and psychosocial wellbeing.

Study description

Background summary

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 symptoms or 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 such as cardiac rehabilitation 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.

Study objective

1. To compare the impact of a 12-month cardiac rehabilitation program (PRO-FIT) vs. an invasive approach including coronary angiography and subsequent coronary revascularization in stable angina pectoris patients on angina symptoms.

2. To evaluate the cost-effectiveness of PRO-FIT compared to routine invasive care in stable angina pectoris patients, as well as cardiovascular events, quality of life, fitness, cardiovascular health, psychosocial wellbeing.

Study design

Multicenter randomized controlled trial

Intervention

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.

Study burden and risks

Recent studies show that routine invasive care does not result in superior effects on re-events or prognosis as compared to non-invasive medical treatment, showing that a conservative approach is safe in patients with SAP. In the PRO-FIT study, the intervention group will receive cardiac rehabilitation on top of medical treatment, which may be perceived as burdensome by some patients, because it requires time and effort from the patients. However, the cardiac rehabilitation program is expected to be beneficial. According to several studies, event rates of exercise training in cardiac patients are approximately 1:50.000 to 1:60.000 exercise hours/year, due to this low number of event rates we expect no additional risks of the intervention.

The extra measurements for this study on top of regular care consist of an exercise test at one-year follow-up and questionnaires every 3 months. These measurements are all minimally invasive and also routinely performed in regular care. Therefore, the nature and extend of the burden and risks associated with study participation are very low.

The control group will receive usual care.

If a patient from the intervention group has signs of clinically worsening symptoms, the patient will be thoroughly evaluated and will receive additional care as needed, whereby also crossover to usual care (i.e. invasive evaluation with a coronary angiogram) will be considered as appropriate.

Contacts

Public
Maxima medisch centrum

De Run 4600
Velhoven 5500 MB
NL
Scientific
Maxima medisch centrum

De Run 4600
Velhoven 5500 MB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Stable angina pectoris with residual anginal symptoms after optimal medical therapy
- 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

Exclusion criteria

An echocardiography and coronary angiography (usual care group) or coronary computed tomography (CT)-angiography (cardiac rehabilitation group) will be performed at baseline to exclude high-risk patients with a reduced left ventricular function (i.e. left ventricular ejection fraction <35%) or left main coronary artery disease. 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-03-2022
Enrollment:	216
Type:	Actual

Ethics review

Approved WMO Date:	30-11-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-12-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-02-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-02-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-03-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-04-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-05-2022

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-07-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 24082
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL77210.091.21