OPTImal CArdiac REhabilitation (OPTICARE) following Acute Coronary Syndromes: A multicenter, randomized, controlled trial to investigate the benefits of an expanded educational and behavioural intervention program.

Published: 13-04-2011
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Primary objective of the OPTICARE study is to evaluate whether patients with acute coronary syndrome (ACS) will derive additional benefit from an extended CR program compared to standard CR.

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

Summary

ID

NL-OMON39177

Source
ToetsingOnline

Brief title
OPTICARE study

Condition

- Coronary artery disorders

Synonym
Acute coronary syndrome

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Capri hartrevalidatie Rotterdam.

Intervention

Keyword: acute coronary syndrome, cardiac rehabilitation, coronary angioplasty, RCT

Outcome measures

Primary outcome

Decrease in cardiac risk factors, higher physical activity and better quality

of life in the intervention group.

Secondary outcome

Earlier return-to-work, less health care consumption, less anxiety and

depression in the intervention group.

Study description

Background summary

Throughout the western world, healthy life style management is becoming increasingly important as the incidence of obesity, hypertension, and diabetes is rising, taking on epidemic proportions. According to the World Health Organisation 75 % of cardiovascular diseases could be prevented by optimal life style management. Since the introduction of primary angioplasty (primary PCI) more patients not only survive an acute myocardial infarction (AMI) but also have a better preserved cardiac function. Hence, the number of patients requiring long time medical care is growing, leading to a concomitant burden on the health care system. Therefore, secondary prevention with an emphasis on lifestyle adjustments should be the cornerstone of modern cardiac rehabilitation (CR). Guidelines for healthy life style management as part of CR are based on results of previous studies. According to these guidelines important goals of CR are smoking

cessation, improved dietary and stress management
and increased daily activity levels. However, there is a considerable gap
between these guidelines and their actual
implementation. This gap could be the cause of the poor adherence to lifestyle
modifications often seen after completion of
standard CR. The life style modifications are often not incorporated into daily
routine. This study may demonstrate the benefits
of extended CR with respect to achieving optimal long term secondary prevention
goals. Implementation of this extended CR
should result in a cost-effective program. If the hypothesis of the proposed
study is confirmed, relative small adjustments to the
current CR program may enhance secondary prevention in patients after an acute
coronary event, improve their quality of life
and reduce health care consumption

Study objective

Primary objective of the OPTICARE study is to evaluate whether patients with
acute coronary syndrome (ACS) will derive additional benefit from an extended
CR program compared to standard CR.

Study design

A sample size of 500 patients in the three treatment arms is needed to detect a
difference of 20% in the main outcome
measures based on a two-sided alpha and a power of 80%.
Patients will be randomized into 2 arms:
1) Control arm: standard CR according to the guidelines: (a) consisting of 2
times a week exercise program of 1.5 hours during
12 weeks, (b) upon request of the patient: participation in multifactorial
lifestyle and risk factor sessions (medical information,
dietary advises and emotional advises, information about risk factors, smoking
cessation program and stress management.
sessions). There is also the possibility for individually based psychological
programs during these 12 weeks.
2) First treatment arm: extended CR: (a) standard CR consisting of 2 times a
week exercise program of 1.5 hours during 12 weeks.
(b) Participation in multifactorial lifestyle and risk factor sessions: i.e. 4
sessions of 2 hours each: medical information, dietary
advises, risk factors and emotional advises. If applicable, patients will
participate in smoking cessation, dietary and stress
management programs . (c) Individual sessions and a personalized home-based
program to promote an active life style upon
instruction of a physiotherapist and physical activity counselor during and
after completion of rehabilitation. Activity monitors will
be used to provide feedback. (d) Additional compulsory supervised

multifactorial lifestyle and risk management training
sessions of each 2 hours provided at 4, 6 and 12 months.
3) Second treatment arm: COACH intervention arm: intervention starts 2 weeks after ending standard CR and is based on five phonebased coaching sessions at 6 weeks intervals up to 6 months. Each coaching session includes 5 stages: (1) Asking questions to establish patient*s knowledge, attitude and beliefs about their risk factors; (2) Explanation and rationale; (3) Assertiveness training; (4) Goal setting; (5) Reassessment

Intervention

Extended cardiac rehabilitation

Study burden and risks

none

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

Patients who are referred after an acute coronary syndrome for cardiac rehabilitation.
Be able to complete the Dutch language questionnaires.
Able to attend regularly the supervised exercise program.

Exclusion criteria

Hart failure, heart valve disease, congenital disease, psychic or cognitive impairment, severe arrhythmias

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:	Recruitment stopped
Start date (anticipated):	15-09-2011
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO Date:	13-04-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-07-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-03-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-12-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-06-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT01395095
CCMO	NL34278.078.10