Preventive Heart Rehabilitation in patients undergoing elective Open heart surgery to prevent Complications and to improve Quality of life (Heart-ROCQ) - A randomized controlled trial

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to determine whether a pre- and postoperative CR (PRE+POST) program improves the short (up to three months) and long term outcomes (up to one year) after cardiac surgery (i.e. reduction in postoperative surgical complications, readmissions to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Interventional

Summary

ID

NL-OMON42974

Source
ToetsingOnline

Brief title
Heart-ROCQ

Condition

- Therapeutic procedures and supportive care NEC

Synonym
cardiac surgery, cardiovascular surgery

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Edwards, www.edwards.com,St. Jude Medical

Intervention

Keyword: Cardiovascular surgery, Pre- en postoperative rehabilitation, Quality of life, Surgical complications

Outcome measures

Primary outcome

The primary outcome is a composite weighted endpoint of postoperative surgical complications, re-admissions to hospital, major adverse cardiac events and health related quality of life (two domains: physical functioning and physical problem), at three months and one year after surgery.

Secondary outcome

Secondary, this study is designed to evaluate the effect of the cardiac rehabilitation programs on:

- Prolonged stay at the intensive care, the occurrence arrhythmias and rethoracotomies (Complications and events)

- Cardiorespiratory fitness, muscle strength and functional status (Physical health)

- Feelings of anxiety, depression and quality of life (Psychological health)

- Work participation

- Economic evaluation: health care costs, work-related costs and quality adjusted life years (QALYs)

- Physical activity and smoking consumption (Lifestyle risk factors)

- self-efficacy, illness representations (Potential mediators)

Study description

Background summary

Patients undergoing cardiac surgery are at risk of developing perioperative complications and major adverse cardiac events, mainly related to both their preoperative status and type of surgical procedure. Postoperative exercise based cardiac rehabilitation (CR) is an effective therapy to prolong survival and improve quality of life. However, little is known about the effect on post-operative complications, quality of life and return to work of a combined pre- and post-operative CR program encompassing physical therapy, dietary counseling, psychological support and life style management compared to a CR program, which is provided only after cardiac surgery.

Study objective

to determine whether a pre- and postoperative CR (PRE+POST) program improves the short (up to three months) and long term outcomes (up to one year) after cardiac surgery (i.e. reduction in postoperative surgical complications, readmissions to hospital and major adverse cardiac events in conjunction with improvements in the physical component of health related quality of life), when compared to postoperative CR only (POST).

Study design

A randomized controlled trial. Patients are randomized between two standard care CR programs. One group will start the regular CR program after surgery. The other group will be randomized to a combined pre- and postoperative CR program.

Intervention

NA

Study burden and risks

The risks of the study measurements are minimal, because all studied parameters are observational and non-invasive. Questionnaires and physical tests are conducted. Eligible patients are asked to fill in six validated questionnaires additional to standard care for three to four times (baseline, one day before surgery, 3-4 months and one year after surgery). In addition, four

questionnaires (KATZ, PHQ-9, GAD and Rand-36_v2) are collected in standard care as standard care procedure (*Meetbaar Beter*) and are repeated for one to two times. Furthermore, patients are asked to perform four physical tests (6 minutes walking test, grip and leg strength and sit to stand test), which can be conducted in 45 minutes. These tests are performed throughout the rehabilitation program and after surgery at 3-4 months and after one year. Part of these tests are conducted in the context of the CR program.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age >= 18 years
- Accepted for elective coronary bypass surgery, degenerative valve disease or aortic surgery (or combined) under general anesthesia

Exclusion criteria

• Patients accepted for transcatheter aortic valve implantation (TAVI)
• Admitted to the department of congenital heart surgery
• Aortic descendens or dissections
• Elite athletes
• Co-morbidities that prevent participation in one or more program elements (e.g. disorders to the nervous or musculoskeletal system that limits exercise capacity, severe COPD (GOLD class 3-4), addiction to alcohol or drugs/ serious psychiatric illness) or when it is undesirable to exercise (e.g. cardiomyopathie/morrow).
• Other treatment planned that possibly will interrupt the cardiac rehabilitation program (for example on a waiting list for a organ transplantation, preoperative endocarditis or planned chemotherapy for cancer etc.)
• Unable to read and write Dutch

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):	15-05-2017
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO

Date:	17-01-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NCT02984449
CCMO	NL58542.042.16