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# Heart rehabilitation in patients awaiting open heart surgery targeting to prevent complications and to improve quality of life (Heart-ROCQ): study protocol for a prospective, randomised, open, blinded endpoint (PROBE) trial

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## Key points

- The Heart-ROCQ randomised clinical trial is the first to assess the effect of a combined pre- and postoperative cardiac rehabilitation programme compared with a postoperative programme alone.
- The Heart-ROCQ programme is multidisciplinary, assessing a composite primary endpoint of functional status, postoperative complications, readmissions and major adverse cardiac events (MACE).
- The study will assess both short- and long-term effects of cardiac rehabilitation programmes.

## Background information

- Ischaemic heart disease is the primary cause of death in western countries.
- Patients with severe ischaemic heart disease can be treated with cardiac surgery.
- After cardiac surgery, the risk of complications (including arrhythmias, delirium and pulmonary complications) is high.
- The prevalence of modifiable risk factors, such as obesity and hypertension, has increased in recent years.
- Cardiac rehabilitation aims to improve the pre- and postoperative status of patients undergoing cardiac surgery by influencing the underlying cause of cardiovascular disease and optimising the patient's physical, mental and social conditions.
- Postoperative cardiac rehabilitation is part of standard care in the Netherlands.
- Some benefits of pre- and postoperative cardiac rehabilitation programmes have been reported, but evidence about cost-effectiveness and long-term outcomes is lacking.
- Until now, the effect of combined pre- and postoperative cardiac rehabilitation has not been investigated in a randomised study.

## Aim

- To compare the effectiveness of a multidisciplinary pre- and postoperative cardiac rehabilitation programme (Heart-ROCQ) with that of a standard care postoperative cardiac rehabilitation programme in the Netherlands.

## Type of study

- Prospective, randomised, single-centre, open, blinded endpoint trial.

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## Endpoints

- Composite primary endpoint:
  - Functional status
  - Postoperative surgical complications
  - Hospital readmissions
  - MACE.
- Secondary endpoints:
  - All individual components related to complications and events of the composite endpoint
  - Lifestyle risk factors
  - Work participation
  - Length of stay at the hospital
  - Physical and psychological functioning.
- An economic evaluation will also be carried out.

## Methods

### Participants

- Adult patients (n=350) who are accepted for elective CABG, valve surgery, aortic surgery or combined procedures will be randomly allocated to the Heart-ROCQ group or standard care group.
- Exclusion criteria include congenital procedures, TAVR, aortic dissections or aortic descending repair.
- Seventy-five patients were enrolled between May 2017 and December 2018.
- The last patient is expected to be enrolled in July 2021.

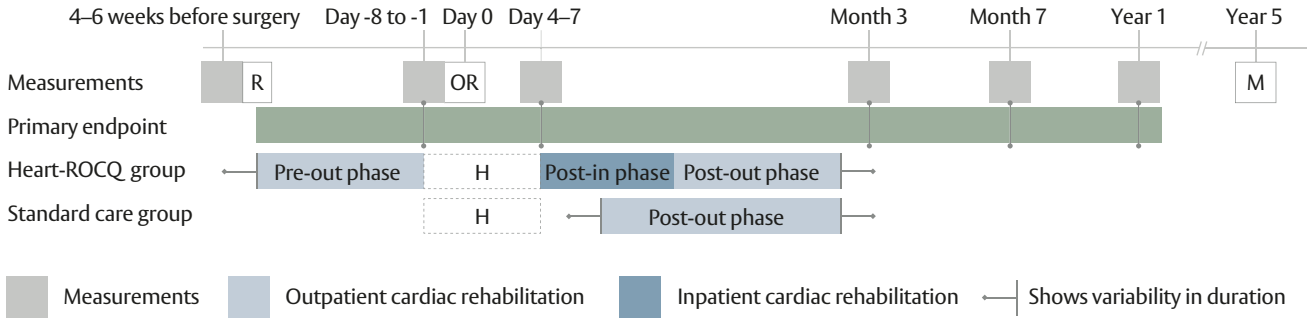
## Study design

- Randomisation is stratified for complexity of surgery (isolated CABG, single non-CABG, two procedures or three procedures), sex and age (≥65 and <65 years).
- Patients who are unwilling to participate in the trial are asked to consent to their routine care data being stored in the Heart-ROCQ study registry. The registry will be used to investigate differences between study patients and non-study patients.

## Heart-ROCQ programme

- The Heart-ROCQ programme involves a preoperative phase (three times per week for a minimum of 3 weeks), postoperative inpatient phase (three times per week for 3 weeks) and an outpatient cardiac rehabilitation phase (two times per week for 4 weeks).
- Treatment modules include physical therapy (strength training and aerobic exercise), psychological sessions and dietary advice.

**Figure 1. Study design of the Heart-ROCQ trial**






H: hospital stay; M: mortality screening; OR: day of surgery; Pre-out phase: outpatient preoperative optimisation phase; Post-in phase: postoperative inpatient cardiac rehabilitation phase; Post-out phase: outpatient cardiac rehabilitation phase; R: randomisation.

## Standard care postoperative programme

- The standard postoperative programme starts 3–6 weeks after discharge and lasts for 6 weeks.
- The programme includes physical therapy (such as strength training and cycling) twice per week and four educational sessions about risk factors and healthy lifestyle.

## Outcome measures and timeline

- Primary endpoints are measured according to a scoring system ranging from 1 to 3 (according to severity). The scores from each event are then combined.
- Secondary endpoints relating to lifestyle, and physical and psychological health are assessed using questionnaires and physical tests.
- Data are collected at baseline, before surgery (1–8 days), at discharge, and at 3, 7 and 12 months after surgery.

## Interim analysis

- The interim analysis will take place when 40% of patients have had measurements 1 year after surgery.
- Premature termination will occur if the primary outcome of one study arm is significantly different ($p<0.001$) from the other arm.

## Economic evaluation

- The probability that the Heart-ROCQ programme is cost-effective compared with standard care will be estimated from a societal perspective.
- Quality-adjusted life years will be estimated using the Euro-Qol Five-Dimensional Questionnaire.
- Results will be reported as an incremental cost-effectiveness ratio.

*This document is a summary of the Hartog J* et al. *paper and covers key information including aim, study type and methods.*

***The full publication is available at:***
***http://bit.ly/Hartog_Heart_ROCQ***

## Abbreviations

CABG: coronary artery bypass grafting
H: hospital stay
Heart-ROCQ: heart rehabilitation in patients awaiting open heart surgery targeting to prevent complications and to improve quality of life
M: mortality screening
MACE: major adverse cardiac events
OR: day of surgery
Pre-out phase: outpatient preoperative optimisation phase
Post-in phase: postoperative inpatient cardiac rehabilitation phase
Post-out phase: outpatient cardiac rehabilitation phase
R: randomisation
TAVR: transcatheter aortic valve replacement



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