Revalidatiebegeleiding van de patiënt voor en na een hartoperatie ter vermindering van complicaties en verbetering van de kwaliteit van het leven (Heart-ROCQ) - een haalbaarheid pilot studie

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21761

Source
NTR

Brief title
Heart-ROCQ

Health condition

Pre- en postoperative rehabilitation
Peri-operative complications
Quality of life
cardiovascular surgery

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: self-financing research

Intervention

Outcome measures

Primary outcome

This study will mainly evaluate post-operative complications (infections, stroke, and heart rhythm problems), duration at the intensive care unit, hospital stay and mortality.

Secondary outcome

Secondary, psychophysical parameters (e.g. delirium, post-operative cognitive decline, disability free survival, quality of life, physical fitness, labor participation, and life style) will be evaluated.

Study description

Study design

There are five timepoints. The first two measurements (four to seven weeks before surgery (T0) and in the last week before surgery (T1) are baseline measurements and evaluate the preoperative outward patient phase in elective patients. The three measurements after surgery (four days after surgery (T2), at the end of the post-operative clinical phase (T3) and at the end of the post-operative outward patient phase (T4) will evaluate the two post-operative phases. A follow up measurement (T5) is performed after three to four months.

Intervention

This intervention consists of 1) a preoperative outward patient clinical optimization period (three times a week for 4-6 weeks), 2) a three week clinical rehabilitation period starting at four days after surgery and a subsequent four week outward patient clinical rehabilitation period (two times a week). During each phase, patients will regularly visit a physical therapist, a dietician and a psychologist to optimize general health and receive advices with regard to lifestyle management. Non-elective patients are starting with the second phase of the intervention.

Contacts

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Eligibility criteria

Inclusion criteria

- Age > 18 years
- Accepted for cardiovascular surgery under general anesthesia
- Patients (age > 18 years) admitted for coronary bypass surgery, valve surgery or aortic surgery (or combined)
- Bed available in the rehabilitation center during the post-operative clinical phase

Exclusion criteria

- Co-morbidities that prevent participation in one program elements (e.g. disorders to the nervous or musculoskeletal system that limits exercise capacity, severe COPD (GOLD class 3-4), non-coping behaviour/ addiction/ serious psychological illness) or when it is undesirable to exercise
- Unable to understand or read Dutch instructions
- Unable to sign informed consent before surgery
- MRSA-positive
- Pregnancy, childbearing potential

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-08-2015
Enrollment:	0
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5114
NTR-old	NTR5246
Other	: 52279

Study results