Physical fitness predictive for morbidity after heartsurgery

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24684

Source
Nationaal Trial Register

Health condition

cardiac surgery

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: UMCG

Intervention

Outcome measures

Primary outcome

The primary parameters are:

-Physical activity (Squash questionnaire)

-Muscle strength (poundsforce) baseline, after 3-4 days post IC and after 3 months

-Incidence of cognitive dysfunction at 3 months (compared to baseline)

-Results of get-up-and-go test (secs) baseline and after 3 months

Secondary outcome

1.Analysis of factors associated with POCD:
Multiple binary logistic regression analysis will be performed to determine the relative strengths of association between potential factors (age, baseline cognitive function, physical inactivity, baseline inflammatory markers) and POCD.

2.Correlation analysis and ANOVA after dichotomisation of physical activity and fitness with morbidity and outcome variables

Study description

Study objective

To assess perioperative physical activity and fitness, and muscle strength in cardiac surgical patients and to explore the association with POCD after heart surgery

Study design

3 months

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

•In order to be eligible to participate in this study, a subject must meet all of the following criteria: Scheduled for elective cardiac coronary surgery, and booked for routine clinical assessment on the cardiosurgical preoperative screening unit.

•Age 55 years and older

•Able to stand and walk independently

•Able to participate in the online screenings module for cognitive function (ie able to operate a computer touch pad or mouse, and to read large text on a computer screen).

•They should be prepared to allow a researcher to visit them at home 3 months after their operation.

•Patients need to be able to perform the handgrip strength test on both sides.

Exclusion criteria

•A potential subject who meets any of the following criteria will be excluded from participation in this study: Extended postoperative ICU stay is expected.

•Inability to understand or read Dutch instructions

•Recent history of depression or severe anxiety

•History of dementia or other neurological disorders

•History of stroke, or other severe cerebrovascular insults

•Patient is not able to perform get-up-and-go test or any of the other tests

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-11-2014
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-10-2014
Application type:	First submission

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	NL4716

Register	ID
NTR-old	NTR4861
CCMO	NL2014 Fitness

Study results