Assessment of Physical Fitness and Activity in cardiac surgery patients in relation to cognitive function decline and perioperative morbidity

Published: 10-10-2014
Last updated: 21-04-2024

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41968

Source
ToetsingOnline

Brief title
Physical fitness predictive for morbidity after heartsurgery

Condition

- Coronary artery disorders
- Cognitive and attention disorders and disturbances

Synonym
postoperative cognitive dysfunction/concentration and memoryloss after surgery

Research involving
Human

Sponsors and support

Primary sponsor: anesthesiologie- onderzoeksbureau

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: morbidity, Physical activity, Physical fitness, Postoperative Cognitive Dysfunction

Outcome measures

Primary outcome

The main study parameters will be:

• Pre-operative levels of physical activity as assessed by the SQUASH

questionnaire and the SenseWear activity meter

• Pre-operative mobility/fitness as assessed by the get-up-and-go test

• Pre- and operative muscle strength, as assessed by a simple mechanical device.

• Development of POCD, defined as a decline of cognitive performance (relative

to baseline) of >= 2 SD in 2 or more of the 4 cognitive tests.

Secondary outcome

Secondary outcome parameters will include routinely recorded process and

outcome variables.

Study description

Background summary

Post-operative cognitive decline (POCD) is a common after cardiac surgery, particularly in the elderly. Epidemiological studies show that the risk factors include advanced age and low baseline cognitive function. The reasons for this are uncertain. Some theories tend to focus on the inflammatory response to surgery and anesthesia, but in a recent study at the UMCG we found no association between inflammatory marker levels and POCD in patients undergoing coronary artery bypass surgery. We have not entirely abandoned the inflammation hypothesis (and are collaborating with the group of Dr Barbara van Leeuwen on a larger scale study - METC 2014/095 - of the relationship between perioperative inflammatory state and POCD) in patients undergoing oncological surgery). We

also plan to examine other possible hypotheses.
In general physical activity is associated with better health, and muscle strength is a marker for physical fitness. Recent work in elderly non-surgical population groups suggests an association between low muscle mass and muscle weakness, and cognitive decline. The reasons for this association are not clear, although there is some evidence to suggest physical activity and a good muscle mass suppresses harmful inflammatory activity. The relation between preoperative activity and physical fitness, and the incidence of POCD in cardiac surgical patients is unknown. We hypothesize that preoperative and postoperative physical inactivity and poor fitness may be associated related towith POCD and other adverse outcomes changes in cardiac surgical patients.

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

Observational study

Study burden and risks

In this study the participants will have no benefit. Due to the observational and non-invasive nature of the study, the risks of participation are minimal. The burden of participation is modest. In addition to usual clinical care, only cognitive tests, questionnaires and fitness tests will be applied. Patients selected for the study will be asked to complete the SQUASH questionnaires about their physical activity before and 3 months after, their operation. It takes about 10 minutes to do this. CogState tests (computerized cognitive function tests) will be performed 3 times - a practise run and a baseline test before surgery and then again 3 months after surgery. Before the CogOGsState test the patient will be asked to complete a HADS (anxiety and depression) questionnaire. It takes a couple of minutes to complete the HADS, and about 15 mins to complete each battery of CogsState tests. In order to get an impression of physical fitness, hand grip strength and the get-up-and-go test will be performed. The hand grip strength will be measured at the preoperative screening clinic and also after 3 days and again 3 months after surgery. The timed get-up-and-go test will be performed twice at the pre-operative screening visit and 3 months after surgery. The patient is asked for this test to stand up (from sitting), walk 3 metres, and return to the sitting position, if possible three times. General health perception and quality of life will be assessed with the SP36 questionnaire and the EQ 5D test, both performed pre and 3 months postoperative. These questionnaires take a few minutes

Contacts

Public
Selecteer

hanzeplein 1
groningen 9713 EZ
NL
Scientific
Selecteer

hanzeplein 1
groningen 9713 EZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Scheduled for elective cardiac coronary surgery, and booked for routine clinical assessment on the cardiosurgical preoperative screening unit.
- 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

- Exentended 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

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-12-2014
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	10-10-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-01-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Not approved

Date:	05-05-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-09-2015
Application type:	Amendment
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
CCMO	NL49262.042.14