The influence of Anesthesia Geriatric Evaluation on predicting health related quality of life after cardiac surgery in elderly patients

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1. To determine the influence of frailty on predicting an increase in HRQL in elderly cardiac surgery patients .2. To develop an AGE score for predicting an increase in HRQL after cardiac surgery based on surgical risk factors, comorbidities and…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON46934

Source
ToetsingOnline

Brief title
AGE

Condition

- Cardiac therapeutic procedures

Synonym
frailty, vulnerability, weakness

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Maatschap Anesthesiologie St Antonius Ziekenhuis en vakgroep Vitale Functies UMC Utrecht

Intervention

Keyword: cardiac surgery, elderly, frailty, preoperative risk stratification

Outcome measures

Primary outcome

Primary endpunt is an increase >4 points of the physical or mental component

score of the SF-36 health status 12 months after cardiac surgery.

Secondary outcome

Secundary endpoints are incidence of postoperative complications, length of ICU

and hospital stay, HRQL at 3 months, mortality at 30 days and 12 months.

Study description

Background summary

Cardiac surgery in elderly patients is associated with risk of postoperative morbidity, mortality, loss of self-reliance and decreased health related quality of life (HRQL). Such risk is further increased in frail patients.
Frailty results in loss of functional capacity and is characterised by weight loss, sarcopenia and decreases physical activity. The influence of frailty on postoperative outcome after cardiac surgery is not implemented in current international risk prediction models.

Study objective

1. To determine the influence of frailty on predicting an increase in HRQL in elderly cardiac surgery patients .
2. To develop an AGE score for predicting an increase in HRQL after cardiac surgery based on surgical risk factors, comorbidities and frailty.
3. To determine the additional predictive effect of pre-operative non-invasive measurement of AGEs (Advanced Glycation Endproducts) using skinautoflurenscence in predicting an increase in HRQL.

Study design

Prospective, observational, cohort study. Patients are followed up for 1 year. Primary endpoint is an increase in HRQL.

Study burden and risks

This is an observational study, there is no associated risk for the patient. It takes 30 minutes to perform the additional questionnaire, 3 physical tests and 1 AGE reader test. It takes 9 minutes to complete the SF-36 health status questionnaire at 3 and 12 months each.

Preoperative screening at the anesthesiology outpatient clinic
Study patients undergo regular anesthesia screening prior to surgery at the outpatient anesthesia clinic, similar to patients not included in the study. The results of the additional questionnaire and tests hold no consequences for whether or not the patient proceeds to surgery. After visiting the outpatient clinic a study patient receives regular preoperative cardiac care, similar to patients not included in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

age >=<=70
elective cardiac surgery

Exclusion criteria

age <70
urgent cardiac surgery
noncardiac surgery

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2015
Enrollment:	560
Type:	Actual

Ethics review

Approved WMO

Date:	30-06-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-01-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-10-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-05-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-11-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL53243.100.15