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

Published: 30-06-2015 Last updated: 19-04-2024

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

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**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

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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
Туре:	Actual

## **Ethics review**

#### Approved WMO

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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

ССМО

**ID** NL53243.100.15