Evaluation of the association between heart type fatty-acid binding proteins and high sensitive troponin and postoperative myocardial infarction in patients undergoing cardiac-surgery

Published: 25-03-2015
Last updated: 20-04-2024

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Myocardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON41530

Source
ToetsingOnline

Brief title
Biomarkers for postoperative myocardial infarction in cardiac-surgery

Condition

- Myocardial disorders

Synonym
heart attack, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac surgery, heart-type fatty acid binding protein, myocardial infarction, troponin

Outcome measures

Primary outcome

Measurements: From all patients* blood samples will be obtained before, during

and after surgery to measure H-FABP en troponin levels. Other relevant

information will be obtained from the Electronic Patient Record system and from

the Anesthesia Information and Management System (AIMS).

The primary end-point is myocardial infarction. The occurence of postoperative

myocardial infarction is imported from the Board Heart interventions

Netherlands registry (BHN registry). This particular item is standardly filled

out for all cardiac surgery patients in this hospital by the department of

cardiology independent of this research.

Secondary outcome

The secondary endpoint is mortality and hospital length of stay.

Study description

Background summary

Myocardial infarction and subsequent myocardial injury after cardiac surgery occurs in 7-15% of patients undergoing cardiac surgery and is associated with an increased length of stay, and reduced short- and long-term survival. Cardiac troponin is considered to be a cornerstone in the diagnosis of a myocardial

infarction. Heart-type Fatty Acid-Binding Protein (H-FABP) is a new sensitive biomarker for myocardial injury. The effectiveness of using the combination of H-FABP with Troponin to diagnose myocardial injury within 6 hours after the onset of ischemia is well reported. Previous studies in non-surgical patients have associated increased H-FABP with an increased risk of subsequent death and major cardiac events. The prognostic value in cardiac surgery patients has not been studied extensively.

Study objective

The objective is to estimate the association between biomarkers of myocardial injury and myocardial infarction in patients undergoing cardiac surgery. Myocardial infarction will be established with both a new and very early marker of myocardial injury (Heart-type Fatty Acid Binding Proteins) as well as to a known early marker of such injury (Cardiac troponin).

Study design

This is a prospective observational cohort study.

Study burden and risks

For study purposes, nine blood samples will be drawn. The burden for the participants will be minimal as five blood samples are combined with blood sampling for medical care. Four of the blood samples are taken under general anesthesia. The samples will be taken from either the arterial line or central venous line. Risks are negligible as the above mentioned blood sampling methods are all considered as safe.

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

Patients over 18 years, undergoing isolated coronary artery bypass grafting (CABG), isolated valve surgery (aortic valve replacement, mitral valve repair or replacement) or combined CABG and valve surgery in the University Medical Center Utrecht

Exclusion criteria

Emergency surgery, (suspected) sepsis or pulmonary embolism, renal failure (defined as Glomerular Filtration Rate < 40 ml/min).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start

Enrollment:	800
Type:	Anticipated

Ethics review

Approved WMO Date:	25-03-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-09-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL46363.041.14