Minimal invasive imaging of coronary artery disease in patients with asymptomatic myocardial injury after major non-cardiac surgery.

Published: 26-03-2012
Last updated: 01-05-2024

Primary objectivesTo quantify coronary artery disease, determined by minimal invasive imaging techniques, as a cause of post-operative myocardial injury in patients undergoing non-cardiac surgery.Secondary objectiveTo correlate coronary calciumscore…

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

Summary

ID

NL-OMON39130

Source
ToetsingOnline

Brief title
Asymptomatic myocardial injury after non-cardiac surgery

Condition

- Coronary artery disorders

Synonym
Myocardial damage; heart attack

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: Minimal invasive imaging, Myocardial infarction, Post-operative complication

Outcome measures

Primary outcome

Main study parameters:

1. Coronary artery disease with luminal narrowing > 50 % in one or more major

epicardial vessels by CT

2. Presence and extent of coronary artery atherosclerosis as measured with

coronary CT

3. Minimal myocardial injury measured by late gadolinium enhancement on MRI

4) Myocardial ischemia on adenosin perfuion MRI

Secondary outcome

Secondary study parameter:

Agatston coronary calcium score.

Study description

Background summary

see also the introduction section of the protocol.
Early peri-operative troponin elevation after non-cardiac surgery is a strong predictor of short and midterm adverse outcome. The diagnosis of peri-operative myocardial injury using troponin assays is known since the early nineties and

its prognostic value is established now. However, intervention studies to improve prognosis of patients with peri-operative myocardial injury have not been conducted so far. A main limitation in this regard is the lack of knowledge about the pathofysiologic mechanisms behind postoperative troponin elevation.
We hypothesize that novel minimal invasive cardiac imaging techniques such as coronary CT-angiography and MRI may be of help to estimate the risk of coronary artery disease as a cause of peri-operative myocardial injury. Identification of patients with coronary artery disease in the immediate postoperative period allows anti-ischemic therapy for prevention of future adverse events.

Study objective

Primary objectives

To quantify coronary artery disease, determined by minimal invasive imaging techniques, as a cause of post-operative myocardial injury in patients undergoing non-cardiac surgery.

Secondary objective
To correlate coronary calciumscore to post-operative troponin levels.

Study design

Study design
This is a prospective observational study, designed to assess coronary artery disease with minimal invasive techniques, i.e. without classic coronary angiography, in patients with peri-operative myocardial injury after non-cardiac surgery.

Inclusion criteria:
1. Non cardiac surgery with a planned minimal postoperative hospital stay of 2 nights
2. Elective or emergency surgery
3. Age > 60 year.
4. Troponin-I elevation in the first 3 post-operative days: > 0.01 ng/ml.
5. No clinical symptoms of myocardial ischemia.

Exclusion criteria:

1) Perioperative troponin elevation due to other factors than coronary artery disease such as proven pulmonary embolism or sepsis.
2) Perioperative ST-elevation myocardial infarction (STEMI)
3) Perioperative symptomatic angina with troponin elevation

4) Patients with a history or ECG-signs of myocardial infarction
5) Patients with pre-existent heart failure, left ventricular dysfunction, significant valvular disease or left ventricle hypertrophy.
6) Patients with significant valvular disease or left ventricle hypertrophy determined post-operatively with echocardiography.
7) Contra-indication for CMR such as claustrophobia or metal prosthesis.
8) Allergic reaction to CT-contrast or gadolinium.
9) Renal dysfunction with GFR < 30 ml/min, as determined after the operation
10) Unstable hemodynamics or other conditions disabling transport to the Radiology department.
11) Expected major discomfort or substantial increase in pain sensation at the time of undergoing CCTA or CMR.
12) Admission at the ICU
13) Poor prognosis due to other medical conditions e.g. malignancy
14) Second or third degree atrio-ventricular block on the ECG

Study burden and risks

Both cardiac imaging techniques are minimal invasive with a low risk of an anaphylactic reaction and kidney function depression due to the contrast use with the CCTA.
Patients are excluded beforehand if known with allergic reactions on contrast agents
and if known with severe renal failure. Nonetheless, patients are admitted in the hospital
and any adverse reaction in relation to the study procedures will be documented and reported
to the METC and CCMO. Some patients will undergo the MRI in an outpatient setting, according to a standard care protocol.

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

Major non-cardiac surgery with > 2 overnight stay
Troponin elevation post-operatively: > 0.01 ng/ml
Age > 60 year
No clinical signs of myocardial ischemia

Exclusion criteria

Hemodynamic instability
Contra-indication for MRI e.g.metal prosthesis
Previous myocardial infarction
Severe renal failure: GFR < 30 ml/min
Contrast allergy
AV-block grade 2 or 3.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-09-2012
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	26-03-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-02-2013
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	NL38879.041.11