Troponin Elevation After Major noncardiac Surgery

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Primary objective To investigate and compare the independent prognostic effects of the different PMI phenotypes (myocardial infarction and noninfarct troponin elevation) and noncardiac MAPE on disability in patients undergoing elective noncardiac...

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

Summary

ID

NL-OMON55521

Source
ToetsingOnline

Brief title
TEAMS

Condition

- Myocardial disorders

Synonym
heart injury, myocardial injury

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: biomarkers, myocardial injury, non-cardiac sugery

Outcome measures

Primary outcome

Disability is expressed in terms of the WHODAS 2.0 which is based on different functional domains, including cognition, mobility, self-care, getting along, life activities and participation.

Secondary outcome

- Disability free survival is defined as being alive with a WHODAS 2.0 score <= 25% and no increase of the preoperative score >= 25% at 6 months after surgery.

- An in-hospital major adverse postoperative events (MAPE), which could be distinguished in:

o Major adverse cardiac event (MACE), which is defined as the composite endpoint of cardiovascular death, non-fatal myocardial infarction, non-fatal cardiac arrest, non-fatal ventricular fibrillation, non-fatal ventricular hemodynamic compromise and atrial fibrillation requiring cardioversion.

o Noncardiac MAPE, which is defined as a composite outcome consisting of respiratory disorders (including pneumonia and respiratory failure), pulmonary embolism, sepsis and/or systemic inflammatory response syndrome (SIRS), renal failure, reoperation and unplanned ICU admission.

- In hospital all-cause mortality

- Length of hospital stay

- 6-month MACE

- 6-month all-cause mortality

Study description

Background summary

Patients undergoing major noncardiac surgery may experience major adverse postoperative events (MAPE), which lead to mortality and morbidity. Such complications are hard to diagnose, as typical symptoms are often not present in most often postoperative patients (e.g., chest pain may be masked by pain medication).
Routinely measuring cardiac troponins during the perioperative period is an accurate method to confirm diagnosis of postoperative myocardial injury (PMI). In patients aged > 60 years undergoing intermediate or high risk noncardiac surgery, PMI occurs in 15% of the patients. Approximately one third of them develops an often symptomless myocardial infarction. However, PMI is also associated with other cardiac and noncardiac pathologies including heart failure, arrhythmias, pulmonary embolism, sepsis and renal failure. Therefore, we consider PMI as either myocardial infarction or noninfarct troponin elevation (NITE). Currently, the etiology and long term effects of PMI on disability are unknown. Differentiation of patients with PMI in the appropriate disease entity will hopefully contribute to more suitable treatment and prevention of major complications.
The aim of this study is to investigate and compare the independent prognostic effects of the different PMI phenotypes (myocardial infarction and NITE) and noncardiac MAPE on disability. We will be diagnosing the differing PMI phenotypes using clinical evaluation and biomarkers.

Study objective

Primary objective
To investigate and compare the independent prognostic effects of the different PMI phenotypes (myocardial infarction and noninfarct troponin elevation) and noncardiac MAPE on disability in patients undergoing elective noncardiac surgery.

Secondary objectives
1. To investigate and compare the independent prognostic effect of the different PMI phenotypes (myocardial infarction and noninfarct troponin elevation) and noncardiac MAPE on disability free survival in patients undergoing elective noncardiac surgery.
2. To examine whether (combinations of) perioperatively measured biomarkers are associated with in-hospital MAPE in patients undergoing elective noncardiac surgery. MAPE are divided in different subtypes, including:

a. MACE, which is defined as the composite endpoint of cardiovascular death, non-fatal myocardial infarction, non-fatal cardiac arrest, non-fatal ventricular fibrillation, ventricular hemodynamic compromise, atrial fibrillation requiring cardioversion, pulmonary embolism and stroke.
b. Noncardiac MAPE including sepsis, renal failure, unexpected intensive care unit (ICU) admission and respiratory disorders.
c. All-cause mortality
3. To examine whether (combinations of) perioperatively measured biomarkers are associated with 6-month MACE and all-cause mortality in patients undergoing elective noncardiac surgery.
4. To assess the added value of the perioperatively measured biomarkers on top of the currently used Revised Cardiac Risk Index (RCRI) to predict MACE after noncardiac surgery.
5. To externally validate existing prediction models to predict postoperative outcomes in patients undergoing noncardiac surgery.

Study design

This prospective observational cohort study includes patients, aged 60 years and older, undergoing elective intermediate or high risk noncardiac surgery under spinal or general anesthesia with an expected postoperative hospital admittance of at least 24h. All patients are required to visit the preanesthesia outpatient clinic for preoperative consultation. In addition to care as usual, extra blood samples will be taken preoperatively and postoperatively up to three days after surgery to determine the following biomarkers: high sensitive troponin, brain natriuretic protein, C-reactive protein, creatinine and hemoglobin. At postoperative day 1, extra to routine care noninvasive imaging (i.e. electrocardiography and if possible a transthoracic echography) will be performed. Preoperatively measured biomarkers are considered baseline measurements. Biomarker values will be blinded from treating physicians in case this particular biomarker was not measured in routine care. In-hospital MAPE will be monitored including cardiac events, respiratory failure, pulmonary embolism, sepsis, renal failure and mortality. In addition, patients will be asked to fill out the WHODAS 2.0 questionnaire preoperatively and 6 months after their surgery to assess disability. Their general practitioners (GPs) will be approached to determine whether MACE and/or mortality have occurred during the 6 months follow up after surgery.

Study burden and risks

In addition to routine care, patients will be asked to fill out the WHODAS 2.0 before surgery and additional blood will be drawn (7 cc in total) before induction of anesthesia. Postoperatively, extra blood will be taken up to three days after surgery (7 cc in total each time) during routine blood draws. At postoperative day 1, an electrocardiogram (ECG) and if possible a transthoracic

echo (TTE) will be performed. Six months after surgery, patients will be asked to fill out the WHODAS 2.0 for the second time and their GPs will be approached to assess whether clinically relevant events have occurred. The study is associated with a negligible risk as only noninvasive imaging procedures will be performed and blood will be drawn. The treating physician will be notified in case any unexpected findings from the ECG and TTE are observed meaning that participation to this study could lead to early recognition of heart disease.

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 are >= 60 years old;
- Patients undergo major non-cardiac surgery defined as all non-cardiac surgical procedures requiring an expected hospital stay of at least 24 hours;

- Patients undergo elective surgery, defined as surgery that that has been preceded by a preoperative consultation at the anesthesia preoperative screening outpatient clinic.

Exclusion criteria

- Patients unable to fully comply to study needs (e.g. legally incapable patients or patients unable to communicate in Dutch or English).
- Patients with an American Society of Anesthesiologists (ASA) Physical status 5

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2018
Enrollment:	650
Type:	Actual

Ethics review

Approved WMO Date:	17-11-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	17-05-2019

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-01-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-02-2022
Application type:	Amendment
Review commission:	METC NedMec

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
ClinicalTrials.gov	NCT03408522
CCMO	NL62040.041.17