Platelet reactivity and post-operative myocardial injury after major non-cardiac surgery (PROMISE).

Published: 28-04-2017
Last updated: 16-04-2024

1. To determine if pre-operative/post-operative platelet function/activation is associated with peak postoperative cTn levels. 2. To determine if peak postoperative inflammatory biomarker levels (IL-6, hs-CRP) are associated with peak postoperative...

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

Summary

ID

NL-OMON47812

Source
ToetsingOnline

Brief title
PROMISE

Condition

- Vascular therapeutic procedures

Synonym
asymptomatic postoperative troponin elevation, heart injury after surgery, Myocardial injury after noncardiac surgery

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: R en D Anesthesie en R en D Cardiologie

Intervention

Keyword: Myocardial injury, Platelet reactivity, Vascular surgery

Outcome measures

Primary outcome

Peak postoperative cardiac troponin level

Secondary outcome

Length of stay, myocardial infarction, stroke, death during hospital stay.

Study description

Background summary

Asymptomatic cardiac troponin (cTn) elevation after major non-cardiac surgery is a strong predictor of postoperative morbidity and mortality. (1,2) However, the aetiology of such postoperative myocardial injury (PMI) remains unclear. Currently, it is believed that PMI is primarily attributable to an oxygen supply / demand mismatch in the presence of pre-existent coronary artery disease or - less often - of rupture of an atherosclerotic plaque leading to epicardial thrombosis and thromboembolism. (3) Platelets play a key role in hemostasis and thrombosis and (on-treatment) platelet reactivity has been demonstrated to be associated with the occurrence of atherothrombotic events. Whether or not platelet reactivity plays a role in the pathophysiology of PMI is unknown.

Study objective

1. To determine if pre-operative/post-operative platelet function/activation is associated with peak postoperative cTn levels.
2. To determine if peak postoperative inflammatory biomarker levels (IL-6, hs-CRP) are associated with peak postoperative cTn levels.

Study design

single center, observational cohort study

Study burden and risks

All patients will undergo routine anesthesia screening at the outpatient clinic, during which general cardiac and pulmonary risk factors are evaluated and a standardized physical examination is performed. At time of pre-operative hospital admission a baseline ECG is performed for study purposes. In the OR an arterial line is placed (routine care) and the first additional blood samples are collected for study purposes. Patients are transferred to the ICU after surgery (routine care). At time of ICU admission and at 24 and 48 hours after surgery additional blood samples are collected for study purposes. After 48 hours no more visits of the research team are performed. Patients are followed up using the electronic patient file until hospital discharge, with a maximum of 30 days.

Contacts

Public
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3430 EM
NL
Scientific
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3430 EM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient must meet ALL of the following criteria:
* Males or females > 21 years of age and < 85 years
* Undergoing elective open abdominal vascular surgery
* On pre-operative ascal maintenance therapy

Exclusion criteria

1) Patients who are unable to give informed consent or have life expectancy of < 1year
2) Subjects who have received thrombolytic therapy within 24 hours or GpIIb/IIIa-inhibitors within last 30 days
3) Subjects who had an acute coronary syndrome within the last 30 days
4) Subjects with a contra-indication to anticoagulation or at increased bleeding risk
a. Past or present history (<1 year) of bleeding from gastrointestinal (haematemesis) melena, frank bleed in stool or visible haematuria
b. Known platelet count (<100,00/mm3) or coagulopathy or platelet disorder
c. History of major recent (<30 day) surgery or trauma
5) Known Hb <6.5 mmol/L11g/dl or HCT <33%

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):	28-02-2018
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	28-04-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-03-2019
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	NL57157.100.16