Blood transfusion study in patients at risk for cardiac complications after non-cardiac surgery.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25732

Source
Nationaal Trial Register

Brief title
PETS

Health condition

Myocardial ischemia, blood transfusions, cardiac risk factors, troponin, anemia, surgery
Myocardiale ischemie, bloedtransfusie, cardiale risico factoren, troponine, bloedarmoede, chirurgie.

Sponsors and support

Primary sponsor: Erasmus University Medical Center
Source(s) of monetary or material Support: Initiator

Intervention

Outcome measures

Primary outcome

The primary endpoint is a composite endpoint of all cause mortality, myocardial infarction or

unscheduled coronary revascularization up to 30 days after randomization. Myocardial infarction is defined as the detection of a rise and/or fall of cardiac biomarker values with at least one value above the 99th percentile upper reference limit and with at least one of the following:
(1) symptoms of ischemia, (2) new or presumed new significant ST Segment T wave changes or new left bundle branch block. Development of pathological Q waves in the ECG or (3) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality. Unscheduled coronary revascularization is defined as any percutaneous coronary intervention (diagnostic as well as acute revascularization).

Secondary outcome

Secondary endpoints include the rates of each of the individual components of the primary endpoint.

Study description

Background summary

Topic:

Anemia is a common condition in the perioperative phase and is associated with worse postoperative
cardiovascular outcome. It is unknown whether anemia has a causal relationship with postoperative adverse cardiac complications or that anemia is a marker of ‘unknown disease’ and that therapeutic interventions,
aimed at decreasing the height of the anemia, do not decrease the risk for adverse events. The current guidelines support a restrictive transfusion strategy and advocate a transfusion trigger of 6.0 mmol/l (9.7 g/dl) for patients at high risk for adverse cardiovascular events. Recent studies have shown that especially patients
at the highest risk for postoperative myocardial ischemia might benefit from a higher transfusion trigger in the perioperative period.

Research aim:
The primary objective of this study is to assess whether
a liberal (6.5 mmol/l) transfusion strategy compared to a restrictive (6.0 mmol/l) transfusion strategy lowers the incidence of major adverse cardiac events (MACE). MACE is defined as a composite endpoint of all-cause mortality, myocardial infarction or unscheduled coronary revascularization up to 30 days after randomization.

Research aim:

Our study focuses on the relationship between anemia and postoperative cardiac ischemia. The main objective of our study is to determine if a causal relationship exists between immediate postoperative hemoglobin levels and the occurrence of postoperative troponin release.

Approach:

The proposed study is a randomized, parallel, two-group multicenter trial. Elective, high-risk non-cardiac
surgery patients will be included if the patients hemoglobin level has fallen below the indicated transfusion
threshold. Patients are randomly allocated to liberal threshold transfusion or restrictive threshold transfusion
strategy. The primary endpoint is the incidence of postoperative troponin release in the first three days after
surgery.

Study objective

It is unknown whether anemia has a causal relationship with postoperative adverse cardiac complications or that anemia is a marker of 'unknown disease' and that therapeutic interventions, aimed at decreasing the height of the anemia, do not decrease the risk for adverse events. We hypothesize that patients at the highest risk for postoperative myocardial ischemia might benefit from a higher transfusion trigger in the perioperative period.

Study design

Preoperative hemoglobin and troponin values will be obtained within 48 hours before surgery. Troponin as well as hemoglobin concentration are measured on postoperative days 1, 2 and 3 (or before discharge).

Intervention

The primary aim of our study is to compare a liberal (6.5 mmol/l (10.9 g/dl)) transfusion strategy to a restrictive (6.0 mmol/l (9.7 g/dl)) transfusion strategy on postoperative troponin release after non cardiac surgery. The assigned transfusion strategy is followed until the third postoperative day or discharge (whichever comes first).

Contacts

Public
Department of Anesthesiology
Erasmus Medical Center
s-Gravendijkwal 230
Felix Lier, van
Rotterdam 3015 CE
The Netherlands
-
Scientific
Department of Anesthesiology
Erasmus Medical Center
s-Gravendijkwal 230
Felix Lier, van
Rotterdam 3015 CE
The Netherlands
-

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: (1) 40 years of age or older presenting for elective non-cardiac vascular surgery with (2) hemoglobin concentrations below 6.5 mmol/l at preoperative admission or during surgery and (3) who have clinical evidence of advanced coronary artery disease. Advanced coronary artery disease is defined as a high sensitive troponin (hs-TnT) value > 99th percentile during preoperative screening for vascular surgery patients at the outpatient clinic.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
(1) if a patient refuses blood transfusions for religious or other reasons, (2) has clinically recognized acute myocardial infarction within 30 days before study entry (randomization), (3) has previously participated in the trial, (4) is actively bleeding at the time of randomization or (5) if the patient is unable to provide a valid informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2015
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	17-01-2012
Application type:	First submission

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
NTR-new	NL3090
NTR-old	NTR3244
Other	- : -
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
2009 van Lier, F. et al., Effect of chronic beta-blocker use on stroke after noncardiac surgery. Am J Cardiol, 2009.
2009 Poldermans, D. et al., Perioperative strokes and beta-blockade. Anesthesiology, 2009.
2009 Perioperative Cardiovascular Risk Identification and Modification Textbook: Myocardial Ischemia: Causes, Symptoms and Treatment, Nova Publishers.
2010 van Lier, F. et al., Impact of prophylactic beta-blocker therapy to prevent stroke after noncardiac surgery. Am J Cardiol, 2010.
2011 van Lier, F. et al., Epidural analgesia is associated with improved health outcomes of surgical patients with chronic obstructive pulmonary disease. Anesthesiology, 2011.
2011 van Lier, F. et al., Statins in Intensive Care Medicine: still too early to tell. Netherlands Journal of Critical Care, 2011.
2011 van Lier, F. et al., Risk modification for postoperative pulmonary embolism: Timing of postoperative prophylaxis. Thromb Res, 2011.