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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25732

Bron
Nationaal Trial Register

Verkorte titel
PETS

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus University Medical Center
Overige ondersteuning: Initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2015
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-01-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3090
NTR-old	NTR3244
Ander register	- : -
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
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.