Perioperative Transfusion Study (PETS): does a liberal transfusion protocol improve outcome in high-risk cardiovascular patients undergoing non-cardiac surgery?

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON41766

Source
ToetsingOnline

Brief title
Perioperative Transfusion Study (PETS)

Condition

- Coronary artery disorders
- Central nervous system vascular disorders

Synonym
Myocardial ischemia;heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,European Society of Anaesthesiology (ESA)

Intervention

Keyword: Blood transfusion regime, Myocardinfarction, Peri-operative

Outcome measures

Primary outcome

The main endpoint of the study is the incidence of MACE within 30 days of randomization. MACE is defined as a composite endpoint of all-cause mortality, myocardial infarction or unscheduled coronary revascularization up to 30 days after randomization.

Secondary outcome

The secondary endpoint is to assess the rates of each of the individual components of the MACE composite endpoint at 30 days in both transfusion strategies. The tertiary endpoint is to assess incidence of pneumonia, wound infection, transfusion adverse reactions, venous thromboembolism, delirium and stroke in both transfusion strategies.

Study description

Background summary

Myocardial infarction and ischemic cardiac complications are very common after noncardiac surgery. Studies show that the incidence of perioperative myocardial infarction varies roughly between 2 and 15%. A major concern is that in around 60% of the patients, ischemic cardiac events occur without symptoms and that these patients therefore do not receive adequate treatment.
Although the majority of peri-operative myocardial infarctions present within

the first 4 days of surgery, and nearly 90% by 7 days, the range of presentation is throughout the entire hospital admission.
In patients with significant coronary artery disease, perioperative myocardial ischemia may be caused by a sustained myocardial supply/demand imbalance due to tachycardia and increased myocardial contractility. This supply/demand imbalance can be exaggerate by anemia. Some studies suggest that preoperative anemia as well as a restrictive transfusion strategy might adversely affect outcome in patients at a high risk for postoperative cardiovascular complications
Apart from the CBO guidelines, no studies are available with regard to optimization of postoperative hemoglobin levels in high risk cardiovascular patients. However, one recently published pilot study shows promising results from a more liberal transfusion regime in patients with recent myocardial ischemia. In a randomized pilot study a more liberal transfusion regime was tested in patients with myocardial infarction, unstable angina and stable coronary artery disease undergoing cardiac catheterization. In the liberal transfusion group a more than 50% reduction in the primary outcome (death, myocardial infarction or unscheduled revascularization) was seen.
It is unsure whether the same preventive effect can be seen in the perioperative phase. We therefore plan to undertake a pilot study

Study objective

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.

Study design

PETS will be a set up a non-blinded randomised controlled (pilot) study including 100 patients.

Intervention

Patients who have provided written informed consent will be randomized to the liberal transfusion or restrictive transfusion strategy once their hemoglobin level has fallen below the upper limit of the liberal transfusion threshold (i.e. 6.5 mmol/l) . Preoperative hemoglobin levels will be drawn as part of standard care the day before surgery. If a patient has a hemoglobin level below the transfusion threshold preoperatively, the patient is allowed to receive a preoperative transfusion to raise the hemoglobin above the lower limit of chosen transfusion strategy. Patients randomly allocated to the restrictive transfusion strategy are permitted to receive transfusions above the restrictive transfusion threshold if patients develop symptoms of anemia, but

will be marked as protocol violation. The assigned transfusion strategy is followed until the third postoperative day or discharge from hospital. Each unit transfused is administered one unit at a time followed by hemoglobin measurement.

Study burden and risks

Patients who included in the study will beexposed to additional bloodsampeling; no more than once a day 15 ml up to 3 days consecutively.
After each blood transfusion a possible transfusion reaction may develeop. The chance of having tranfusion reaction will be minimized by prior to transfusion to carry out a cross-matching in all patients.

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

(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

-If a patient refuses blood transfusions for religious or other reasons,
Has clinically recognized acute myocardial infarction within 30 days before study entry (randomization)
-Has previously participated in the trial
-Is actively bleeding at the time of randomization
-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)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-07-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	21-05-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL52055.078.14