Pre-operative treatment with Erythropoietin and iron supplement for prevention of perioperative blood transfusion in cardiac surgery

Published: 13-01-2014
Last updated: 23-04-2024

Primary objective: To determine the reduction of number of patients who receive blood transfusion perioperatively in the group pre-treated with erythropoietin and iron supplement compared to the control patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON40254

Source
ToetsingOnline

Brief title
EPICS study

Condition

- Cardiac therapeutic procedures

Synonym
bloodloss in cardiac surgery

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: Constructie Catharina ziekenhuis;apotheek Catharina ziekenhuis en de firma Janssen

Intervention

Keyword: cardiac surgery, Erythropoietin/Iron supplement, prevention

Outcome measures

Primary outcome

The number of patients who receive RBC transfusion perioperatively.

Secondary outcome

The mean number of RBC units received per patient in the perioperative period.

Study description

Background summary

Preoperative anemia is a predictor for the outcome after cardiac surgery, and specially leads to increased transfusion of red blood cells (RBC). In patients undergoing cardiac surgery, transfusion is associated with increased mortality and morbidity. Allogenic blood products increase the risk for postoperative infections, mortality and hospital stay. In addition, hospital costs increases by the donation of RBC in the cardiothoracic program in our institution.
In an earlier study of our department, we found that five- and nine-year survival in non-transfused patients undergoing coronary artery bypass grafting (CABG) was better than that of transfused patients and even better than matched populations. Blood transfusion was also identified as an independent predictor of early mortality after CABG. In addition, female gender, lower body surface area (BSA), low preoperative Hemoglobin (Hb), previous cardiac surgery, emergency operation and low preoperative creatinin clearance were found to be independent risk factors for receiving RBC units. Therefore, we sought to create a clinical pathway to minimize transfusion of red blood cells in a selected group of cardiac patients with an increased risk for blood transfusions in our cardiac surgery program.

Study objective

Primary objective: To determine the reduction of number of patients who receive blood transfusion perioperatively in the group pre-treated with erythropoietin

and iron supplement compared to the control patients.

Study design

This is a prospective single center study performed in a randomised setting.

Intervention

Group 1: pre-treated group: patients receive up to two boluses of erythropoietin subcutaneously and one bolus of iron supplement intravenously administered at the outpatient clinic by a special trained nurse prior to surgery. Group 2: control group: no pre-treatment with either medication.

Study burden and risks

The patients in the pre-treated group receive up to 2 times a bolus of erythropoietin and one bolus of iron supplement intravenously administered by a special trained nurse prior to surgery. The surgical intervention that the patients in both groups will undergo is the standard procedure at the Catharina hospital. Apart from the study drug administration in the pre-treated group, no additional invasive procedures will be undertaken. During the hospital stay, next to routine in-hospital assessments on clinical condition and peri- and post-operative data collection, patients will be inquired about symptoms and possible complications. Patients will be requested to come for a follow-up visit 30 days after surgery (+ 7 days) for a follow-up visit, at which time information will be collected concerning clinical symptoms and complications and current medication.
No benefits are expected in the control group. In the pre-treated group, epoetin alfa and Ferinject injections would improve the outcome by increasing the preoperative Hb value without additional risks.

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. Age of 18 years or more undergoing isolated CABG or AVR
2. Preoperative Hb < 7 mmol/l.

Exclusion criteria

1. Off pump surgery.
2. Combination surgery.
3. Re-operation.
4. Emergency operation.
5. Patients with bleeding disturbances;e.g, hemophilia and patients with chronic liver disease.
6. Concomitant use of cyclosporine prior to, during or following surgery
7. Female patients who are pregnant or planning to become pregnant.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-12-2014
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Eprex
Generic name:	Erythropoetin
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Ferinject
Generic name:	Iron(III)carboxymaltose
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	13-01-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	12-05-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	13-10-2014
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
EudraCT	EUCTR2013-005482-40-NL
CCMO	NL47352.060.13