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Pre-operative Iron used as blood sparing technique in orthopedic surgery (total hip replacement and total knee replacement surgery, elective and no revision surgery)

Submission date
30/11/2012

Recruitment status
No longer recruiting

Registration date
23/04/2013

Overall study status
Completed

Last Edited
29/05/2020

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients with anemia (low blood hemoglobin) undergoing orthopedic surgery (e.g. hip or knee replacement) require more blood transfusions. In the Netherlands 70% of hospitals give erythropoietin treatment to this group of patients, but this treatment is expensive. The aim of this study is to find out whether intravenous iron treatment can replace erythropoietin and achieve the same results with lower costs.

Who can participate?
Patients aged over 18 with anemia (low blood hemoglobin) undergoing hip or knee replacements

What does the study involve?
Participants are randomly allocated to be treated with either intravenous iron infusion, erythropoietin, or no intervention (control group). The blood transfusion rates of the three groups are compared.

What are the possible benefits and risks of participating?
Participants may benefit from fewer blood transfusions and a better outcome because of higher hemoglobin levels. Besides very rare side effects of erythropoietin and iron infusions no major risks are expected.

Where is the study run from?
Albert Schweitzer Hospital (Netherlands)

When is the study starting and how long is it expected to run for?
January 2013 to January 2015

Who is funding the study?
Albert Schweitzer Hospital (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL35394.101.11

Study information

Scientific Title
Pre-OPerative Iron used as blood sparing technique in orthopedic surgery (total hip replacement and total knee replacement surgery, elective and no revision surgery): a three-arm randomised controlled trial

Acronym
POP-i

Study objectives
Can intravenous (i.v.) iron therapy can become a method of blood saving therapy for orthopedic surgery and can it replace erythropoietin?

Ethics approval required
Old ethics approval format

Ethics approval(s)

CCMO Maastad Hospital Rotterdam, Is an official ethics committee, 26/09/2012, nr. NL 35394.101.11. METCnr 2011_18

Study design
Three-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Orthopedic surgery

Interventions
Three-arm randomised study in patients with a start Hb level > 6,1 and < = 8,1 mmol/l. Intervention groups will be compared with a control group.

The intervention group will receive i.v. iron infusion or Epo.
The control group will receive no intervention.

Both groups will be transfused following the Dutch Transfusion Guideline (4,5,6, Flexinorm).

Intervention Type
Other

Primary outcome measure
1. Can ferric carboxymaltose effectively reduce RBC transfusion rate compared to controls in elective orthopedic surgery patients?
2. Rate of transfused patients

Secondary outcome measures
1. Does i.v. iron therapy increase preoperative Hb-levels and improve postoperative recovery?
2. Is this i.v. iron therapy also efficient for patients with anemia other than iron deficiency (ACD)?
3. Is infusion of i.v. iron policlinically safe?
4. Cost reductions caused by introduction of i.v. iron therapy - can it then replace Epo?
5. Hospital stay
6. Postoperative complications
7. Time needed for revalidation
8. Measurement of quality of life

9. Total cost treatment
10. Hb-levels pre- and postoperatively
11. Amount of RBC per patient
12. Safety of IV iron

Overall study start date
01/01/2013

Completion date
01/01/2015

Eligibility

Key inclusion criteria
Orthopedic patients > 18 years , either sex, planned for primary total hip and total knee replacement operations with an preoperative > 6.1 mmol/l is > 7 gr/l and < 8.2 mmol/l is < 13.2 gr /l

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1012

Key exclusion criteria
1. Revision operations, preop Hb <= 6.1 mmol/l or > 8.2 mmol/l
2. All patients who wish not to receive blood transfusions
3. Uncontrolled hypertension (Diastolic blood pressure > 95 mm Hg)
4. Patients planned for preoperative autologous donation, cell salvage, wound reinfusion
5. Severe cardiac compromised patients, uncontrolled hypertension, severe disease peripheral arteries, arteria carotis or arteria cerebralis
6. Recent myocardial infarction of CVA or instable angina pectoris or heart failure
7. Prone for thrombosis (f.i. Factor V Leiden)
8. All patients with Hb-globinopathy such as sickle cell anemia or thalassemia
9. Patients with oncological processes except curred malignancy or skin cancer
10. Pregnancy, patients with ciclosporin therapy
11. Impossible to give prophylactic anticoagulant
12. Allergy to Epo or i.v. iron or additives
13 Infected wound, infected prothesis, infectious process at the moment of inclusion
14. Epileptic, chronic kidney and liver insufficiency
15. Iron diseases

Date of first enrolment
01/01/2013

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Albert Schweitzer Hospital
Dordrecht
Netherlands
3300AK

Sponsor information

Organisation
Albert Schweitzer Hospital (Netherlands)

Sponsor details
Albert Schweitzerplaats 25
Dordecht
Netherlands
3311 AT

Sponsor type
Hospital/treatment centre

Website
http://www.asz.nl/

ROR
https://ror.org/00e8ykd54

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Albert Schweitzer Hospital (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration