

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	☐ Prospectively registered ☐ Protocol
Registration date 23/04/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 29/05/2020	Condition category Surgery	☐ 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?
Dr A.W.M.M. Koopman-van Gemert
gemertvanaw@asz.nl

Contact information

Type(s)
Scientific

Contact name
Dr A.W.M.M. Koopman-van Gemert

Contact details
Albert Schweitzerplaats 25
Dordrecht
Netherlands
3300AK
+31 (0)78 6541111
gemertvanaw@asz.nl

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design

Three-arm randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Orthopedic surgery

Interventions

Three-arm randomised study in patients with a start Hb level $> 6,1$ and $\leq 8,1$ 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(s)

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

Key secondary outcome(s)

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 polyclinically 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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 cured 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 prosthesis, 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)

ROR

<https://ror.org/00e8ykd54>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Albert Schweitzer Hospital (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration