“Pre-operatieve Iron” use as blood sparing technique in Orthopedic Surgery (THP en TKP surgery, elective and no revision surgery).

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22057

Source
NTR

Brief title
POP-i study

Health condition

Pre-existing anaemia is a risk factor for increased morbidity, mortality and has been identified as a strong predictor for RBC transfusions. A recent multicenter trial, investigating the efficay of diverse blood saving therapies, showed that erythropoietin reduces transfusion rate with 50%. Patients with Hb-levels > 6,1 mmol/l and <= 8,1 mmol/l, were transfused 3 times more than patients with a Hb-level > 8,2 mmol/l. Epo reduces transfusion rates in this anemic group with 50%. The costs for this policy were however unacceptably high (7300 euro per avoided transfusion). Recently a new type of IV iron products came available. An interesting finding is that use of IV iron was not only effective in iron deficient patients, but also in anaemia of the chronic disorder (ACD), which is present in a large group of anaemic patients (Anker, Davis). We hypothesize if IV iron can replace Epo. We take into account that the IV iron effect will be less than Epo (reduction BT-rate 12% with Epo, 15% with IV iron compared to 24% controlegroup). In this study we compare each intervention with a controlgroup

Inleiding en motivatie.
In dit onderzoek willen wij nagaan of intraveneuze ijzertherapie een rol kan spelen als

bloedtransfusiebesparende techniek in vergelijking met geen behandeling (controlegroep) of Epo. Er is gekozen om niet alleen die patiënten te behandelen met een aangetoond ijzerdeficiëntie, maar alle patiënten met een Hb > 6,1 en ≤ 8,1 mmol/l. Allereerst omdat de data uit de TOMaat studie aangeven dat controlepatiënten met een Hb > 6,1 en ≤ 8,1 mmol/l drie keer vaker getransfundeerd werden dan patiënten met Hb> 8.2 mmol/L, 24% versus 8% (4). Deze Hb grens is tevens de grens die wordt gehanteerd voor de toepassing van Epo, een geaccepteerd en frequent gebruikt, maar dure bloedbesparende interventie. Omdat Epo tegenwoordig in meer dan de helft van de Nederlandse ziekenhuizen wordt toegepast, en dus als standard care mag gelden, wordt ter vergelijking de Epo arm eveneens meegenomen. Er is voor gekozen om voor mannen en vrouwen hetzelfde inclusie Hb te hanteren. Volgens de huidige WHO-criteria hebben vrouwen met een Hb > 7,5 mmol/l geen anemie. Of deze Hb grens ook geldt voor oudere patiënten staat ter discussie (Izaks). Bovendien laat een subanalyse van de data uit de Tomaatstudie zien dat in de controlegroep bij vrouwen met een Hb tussen 7,5 – 8,2 mmol/l het aantal BT halveert (20%) ten opzichte van de groep met een Hb onder de 7.5 mmol/L (47%), maar nog steeds twee keer hoger is dan de groep boven de 8.2 mmol/L (10%) (nog niet-gepubliceerde data).
Gedurende het onderzoek wordt de ijzerstatus van de patiënt in kaart gebracht, zodat achteraf kan worden nagegaan welke vorm van anemie de patiënt had en onderzocht kan worden wat het effect van ijzertherapie is op de diverse vormen van anemie, m.u.v. de controlegroep, waarbij een aangetoonde ijzergebrekanemie (ferritine < 100g/l of transferrine/log (ferritin) ratio > 1.7 (Castel) wel wordt behandeld met orale ijzertherapie (standard care). Verder worden ook de kosten en kwaliteit van leven van alle patiënten bepaald om een inschatting te kunnen maken van het verschil in (kosten)effectiviteit van de behandelstrategieën.

Sponsors and support

Primary sponsor: no sponsor
Source(s) of monetary or material Support: no extern funding source

Intervention

Outcome measures

Primary outcome

Can ferric carboxymaltose effectively reduce RBC transfusion rate compared to controles in elective orthopaedic surgery patients?

Primary endpoints: Rate of transfused patients.

Secondary outcome

1. Is 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?).

Secundary endpoints:

Hospital stay, postoperative complications, time needed for revalidation, measurement of quality of life, total cost treatment, Hb-levels preo- and postoperatively, amount of RBC per patient, safety of IV iron.

Study description

Background summary

Investigated are patients planned for a primary, elective total hip or total knee replacement operation. Patients with a Hb > 6,1 and ≤ 8,1 mmol/l, measured 2 weeks before visit to the preoperative poli of the anesthesiologist, will be included. It will be a three arm, Randomized Controlled trial. Patients in the IV iron intervention group will receive 1 gr i.v. iron on the day care at the day of the visit. Patients in the Epo group will receive 4 weekly injections of 40.000 I.U. of Epo, supported bij oral iron therapy. In the control group patients will receive standard care. In case of measured iron deficiency, patient willen receive oral iron therapy. Al patients will be operated 4 weeks after start of therapy.

Both groups will be transfused following the CBO guideline Blood Transfusion 2011, (4,5,6, Flexinorm).

Study objective

In this research we will investigate if i.v. iron therapy can become a method of blood saving therapy for orthopedic surgery and can replace erytropoietin.

Study design

3 months follow up.

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

Orthopedic patients planned for primary Total Hip and total Knee replacement operations with an preoperative Hb > 6,1 and ≤ 8,1 mmol/l.

Exclusion criteria

1. Revision operations;

2. Preop Hb <= 6,1 mmol/l or > 8,2 mmol/l;

3. All patients who wish not to receive blood transfusions;

4. Uncontrolled hypertension (Diastolic blood pressure > 95 mm Hg);

5. Patients planned for preoperative autologous donation, cell salvage, wound reinfusion;

6. Severe cardiac compromised patients, uncontrolled hypertension, severe disease periferal arteries, art carotis or art cerebralis;

7. Recent myocardial infarction of CVA or instable angina pectoris or heart failure;

8. Prone for trombosis (f.i. Factor V Leiden);

9. All patients with Hb-globinopathy such as sickle cell anemia or thalassemia;

10. Patients with oncological processes except curred malignancy or skin cancer;

11. Pregnancy;

12. Patients with ciclosporin therapy;

13. Unpossible to give prophylactic anticoagulant;

14. Allergy Epo or i.v. iron or additives;

15. Infected wound, infected prothesis, infectious process at the moment of inclusion;

16. Epileptic, chronic kidney and liver insufficiency;

17. Iron diseases.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2013
Enrollment:	1020
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-11-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41610
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3573
NTR-old	NTR3731
CCMO	NL35394.101.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41610

Study results

Summary results
N/A