Effect of the number of epoetin alpha injections on the hemoglobin level of anaemic patients eligible for elective orthopedic surgery

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Primary aim:- What is the increase in hemoglobin concentration between epoetin alpha injection number three and four in patients awaiting orthopedic surgery?Secondary aim:- What is de increase in hemoglobin concentration between epoetin alpha...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Red blood cell disorders
Study type	Observational invasive

Summary

ID

NL-OMON45498

Source
ToetsingOnline

Brief title
Effect of EPO on Hb level of anaemic patients

Condition

- Red blood cell disorders
- Bone and joint therapeutic procedures

Synonym
anemia

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: elective orthopedic surgery, epoetin alfa, hemoglobin level

Outcome measures

Primary outcome

The main study parameter is the increase in Hb concentration after each epoetin alpha injection on day -1 versus day -7 before surgery.

Secondary outcome

Secundary study parameters are the increase in Hb concentration after each epoetin alpha injection on day -14, day -7 and on the day of surgery (day 0). Baseline Hb concentration will be measured on day -21, at the start of the treatment with epoetin alpha.

Safety will be assessed by registration of adverse events, such as nausea and influence-like symptoms.
Adherence to the prescribed treatment (epoetin alpha plus iron) will be assessed by the Medication Adherence Report Scale (MARS) questionnaire.

Study description

Background summary

Elective orthopedic surgery, such as total hip and knee replacement, is associated with severe blood loss. As a consequence, without additional blood saving techniques, approximately half of the patients need a blood transfusion

after orthopedic surgery.
To prevent unnecessary blood transfusion several measures are advised. To improve the preoperative status of the patient iron and epoetin alpha are used.
In standard dose, patients receive 600 IU/kg subcutaneously once weekly for three weeks before surgery and on the day of surgery in combination with iron. In practice, this dosage is fixed at a weekly dose of 40,000 IU.
Nevertheless, recent studies showed conflicting results about the cost-effectiveness of epoetin alpha. As no consensus exists which price is reasonable for the prevention of a blood transfusion, the cost-effectiveness of pre-operative epoetin alpha, is questioned.
It could be hypothesized that a more personalized dosing schedule might increase the cost effectiveness of epoetin alpha and also decrease the incidence of dose depended side effects.
The effect of the number of erythropoietin injections on Hb level of mildly anemic patients eligible for large orthopedic surgery has not been described yet. The aim of this study is therefore to assess the effect of the number of erythropoietin injections on the Hb level of anemic patients awaiting orthopedic surgery. The results of the study will provide a better understanding about the dose-response relationship of erythropoietin on the Hb level of a mildly anemic patient. It will also provide a better understanding about the increase of the Hb level at different baseline Hb levels.

Study objective

Primary aim:
- What is the increase in hemoglobin concentration between epoetin alpha injection number three and four in patients awaiting orthopedic surgery?
Secondary aim:
- What is de increase in hemoglobin concentration between epoetin alpha injection number one to three in patients awaiting orthopedic surgery?
- - What is de increase in hemoglobin concentration between epoetin alpha injection number four and the day of surgery in patients awaiting orthopedic surgery?
- Is the increase in hemoglobin concentration associated with the hemoglobin concentration at baseline?
- What proportion of patients reaches maximal advised hemoglobin concentration of 15 g/dL after each subsequent injection?
- Description of side effects

Study design

This study is an observational prospective cohort study.
No control group will be set.

Study burden and risks

The extent of burden en risks are negligible. The only effect of the study on the participant is the execution of five fingertips and filling in one questionaire.

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

Indication for treatment with epoetin alpha according to current guidelines and the opinion of the anaesthesiologists. Epoetin alpha is prescribed to patients with a preoperative Hb level between 10.0 * 13.0 g/dL, scheduled for elective orthopedic surgery with an expected blood loss of 900-1800 mL.

Exclusion criteria

* Any contra-indication for the use of epoetin alpha (hypersensitivity to epoetin alpha or any component of the formulation, uncontrolled hypertension, pure red cell aplasia due to epoetin alpha)
* Myocardial infarction or cerebral vascular accident within 6 months before inclusion
* Serious coronary disease
* Sickle cell anemia
* Pregnancy or lactation
* Existing use of iron supplementation

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	fingertip
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	10-07-2017
Application type:	First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL58460.091.16

Study results

Date completed: 30-09-2018

Actual enrolment: 45