postoperative intravenous iron injections (Venofer) vs. control in total hip and knee arthroplasty

Published: 26-01-2007
Last updated: 08-05-2024

Evaluate iron metabolism, erythropoiesis and hemoblobin level perioperative in patients treated with postoperative intravenous iron injections compared to controls.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON30673

Source
ToetsingOnline

Brief title
postoperative venofer in total hip and knee arthroplasty

Condition

- Haematological disorders NEC
- Iron and trace metal metabolism disorders
- Therapeutic procedures and supportive care NEC

Synonym
iron defecient anemia

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Fresenius Medical

Care

Intervention

Keyword: arthroplasty, iron-injections, RCT, venofer

Outcome measures

Primary outcome

Change in perioperative parameters of iron metabolism and erythroipoiesis. The main parameter is ret-y which indicates the process of reticylocyte hemoglobinisation.

Secondary outcome

Other parameters are ferritin, transferrin, transferrin receptor and ZPP.

Another secundary outcome is perioperative hemoglobin level and amount of allogeneic blood transfusions in both groups.

Study description

Background summary

Prosthetic surgery is associated with considerable blood loss and blood transfusions are frequently necessary. Blood transfusion is associated with a number of risks and complications, including allergic reactions, transmission of infectious agents, and immunomodulatory effects. These potentials risks of allogeneic blood transfusions have lead to a more restrictive transfusion policy.
Postoperative systemic inflammation is probably the factor which impaired the effect of oral iron therapy. Parenteral iron may act by treating a functional iron deficiency and/or by increasing endogenous erythropoietin synthesis. Faster reversibility of anaemia following iron injection improves quality of the postoperative recover. The effect of venofer on parameters of iron metabolism is unclear.

Study objective

Evaluate iron metabolism, erythropoiesis and hemoblobin level perioperative in

patients treated with postoperative intravenous iron injections compared to controls.

Study design

The study is a prospective randomised clinical trial. All patients will be randomly allocated into a Venofer group, or a control group.

Intervention

Patients in the study group will receive 300 mg intravenous iron sucrose (3 ampuls à 5 ml Venofer) on day 0 and 1 postoperative.

Study burden and risks

Safety of intravenous iron injections has already been proven in the past. Therefore the risks is minimal to develop adverse events or undesired reactions by using Venofer.
The burden is also minimal. The collection of extra blood mainly occurs simultaneously with routine venipunctures.

Contacts

Public
Atrium Medisch Centrum

henry dunantstraat 5
6419 pc heerlen
Nederland
Scientific
Atrium Medisch Centrum

henry dunantstraat 5
6419 pc heerlen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients sceduled for elective total hip or knee arthroplasty with preoperative hemoglobin level above 6.8 mmol/l.

Exclusion criteria

Patients with already threated anemia, patients with hemosiderosis, any active infection, current malignancy, uncontrolled hypertension, operated in 3 weeks before randomisation, having blood transfusions in 3 weeks before randomisation, known hypersensitivity to Venofer or one of its components.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2007
Enrollment:	126
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	venofer
Generic name:	iron sucrose
Registration:	Yes - NL intended use

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	EUCTR2006-004293-27-NL
CCMO	NL13940.096.07