

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

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Haematological disorders NEC
<b>Study type</b>	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 erythropoiesis. 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 secondary 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 periooperative 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

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

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

### Exclusion criteria

Patients with already threatened 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