Intra-articular drain position versus subfascial drain position in autologous blood retransfusion in total hip arthroplasty

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31269

Source
ToetsingOnline

Brief title
Drain position in autologous blood retransfusion

Condition

- Other condition

Synonym
postoperative anemia

Health condition

wondbloed productie

Research involving

Human

Sponsors and support

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

Intervention

Keyword: arthroplasty, drain, RCT, retransfusion

Outcome measures

Primary outcome

The main study parameter is the amount of shed blood used for autologous

retransfusion.

Secondary outcome

Secundary parameters are perioperative hemoglobine levels and the amount of

allogeneic blood transfusions.

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 potential risks of allogeneic blood transfusions have led to a more restrictive transfusion policy. An other alternative to diminish the use of allogeneic blood is postoperative cell saving (Bellovac retransfusion system). During clinical orthopaedic practice variable amounts of shed blood was seen in patients undergoing total hip arthroplasty. As a results variable amounts of retransfusion will occur, which finally can lead to variable need to use allogeneic blood transfusions. A possible factor influencing the amounts of shed blood can be the position of the drain. To our knowledge, there are no studies analysing the effect of the position of the drain on the amount of shed blood, certainly not in patients treated with a retransfusion system .

Study objective

Objective of this study is to evaluate the amount of shed blood in patients treated with a postoperative retransfusion system. The influence of the position of the drain will be analysed by comparing intra-articular position versus subfascial position.

Study design

The study design is a prospective randomised clinical trial. All patients are randomly allocated to group 1 (intra-articulaire drain) or to group 2 (subfasciale drain)

Intervention

In all patients in group 1 the de drain is positioned intra-articular. In all patients in group 2 the drain is positioned subfasciaal.

Study burden and risks

Safety of a retransfusion system has been proven in the past. Therefore the risks are minimal to develop adverse events or undesired reactions. The Bellovac retransfusion system is already used in daily orthopaedic practice. The burden is also minimal. Patients will receive a retransfusion of shed blood within 8 hours after surgery. This will take approximately 15 minutes. Both groups will receive normal peri-operative standard of care. No extra investigations will take place.

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

Patients sceduled for elective total hip arthroplasty and treated with postoperative retransfusion system

Exclusion criteria

Patients with already threated anemia, any active infection, current malignancy, uncontrolled hypertension, operated in 3 weeks before randomisation

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Completed

Start date (anticipated):	23-07-2007
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	21-05-2007
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
CCMO	NL17352.096.07