The effect of duration of wound drainage on allogeneic blood transfusions using a postoperative retransfusion system after major orthopaedic surgery

Published: 11-08-2010
Last updated: 30-04-2024

Is the use of postoperative autologous retransfusion drainage (ARD) systems useful in hip and knee arthroplasty?

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

Summary

ID

NL-OMON35562

Source
ToetsingOnline

Brief title
Bellovac ABT drain duration study

Condition

- Joint disorders
- Vascular therapeutic procedures

Synonym
blood transfusion, osteoarthritits

Research involving
Human

Sponsors and support

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

Intervention

Keyword: duration, retransfusion drain, total joint arthroplasty

Outcome measures

Primary outcome

The primary endpoint is the amount of allogeneic blood transfusions in the

three groups. Allogeneic blood transfusions are given by specific haemoglobin

levels.

Secondary outcome

Secondary endpoints are haemoglobin levels in the perioperative period, and

complications with special focus on wound problems after surgery. Furthermore,

all clinical data will be collected such as length of hospitalisation, co

morbidity and others.

Study description

Background summary

Use of post operative wound drains in hip and knee arthroplasty is still debated. Drainage is said to reduce wound haematoma, improves wound healing and prevents infection. Therefore many patients are treated with wound drainage until the first postoperative day. However, it is also said that continual drainage after surgery will increase the amount of shed blood because the counteraction of haematoma formation will not take place. In addition, drains may act as access route for bacterial contamination of the wound which can cause a periprosthetic infection. This favours no drainage at all. These assumptions are based on results in patients where a drain was used as a drainage system only. However, retransfusion drainage systems after arthroplasty are gaining popularity. These retransfusion systems are used to

reduce the need for allogeneic blood transfusions. It is interesting if the potential benefits outweigh the controversial thoughts in drainage. Therefore we want to evaluate whether drainage, using a retransfusion system, after major arthroplasty is useful at all.

Study objective

Is the use of postoperative autologous retransfusion drainage (ARD) systems useful in hip and knee arthroplasty?

Study design

After inclusion, patients are randomised into three groups. Group 1: no drainage, group 2: drainage for 6 hours after surgery and group 3: drainage for 24 hours after surgery. Randomisation with sealed envelopes (stratification per clinic) will be done at the end of surgery just before wound closure. Shed blood in group 2 and 3 is collected and retransfused 6 hours after surgery. After retransfusion the drain is removed in group 2 whereas the drain is continued for drainage until drain removal the first postoperative morning.

Intervention

An existing intervention will be investigated, autologous retransfusion drainage with the Bellovac® ABT retransfusion system.

Study burden and risks

There are no potential risks for the patients participating in the trial

Contacts

Public
Medisch Centrum Haaglanden

Lijnbaan 32
2501 CK Den Haag
NL
Scientific
Medisch Centrum Haaglanden

Lijnbaan 32
2501 CK Den Haag
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients scheduled to undergo elective major orthopaedic surgery (hip, knee)
- Male and non-pregnant female patients between 18-80 years of age.
- Patients who signed the Ethics Committee approved specific Informed Consent Form prior to surgery.

Exclusion criteria

- Patients with a major surgical procedure during the 12 weeks before the study-related operation.
- No other used alternatives to reduce allogeneic blood transfusions, such as preoperative epoetin alpha (Eprex®) injections or intra-operative cell saving (Sangvia®).
- Clinical or laboratory evidence of untreated iron, folate or vitamin B12 deficiency.
- Recent Myocardial Infarction or CVA (<3 months).
- Dutch language not mastered.
- The patient is pregnant or planning a pregnancy after surgery (or is using inadequate birth control).
- Mentally disabled patients.
- Current malignancy or any active infection.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-11-2011
Enrollment:	570
Type:	Actual

Medical products/devices used

Generic name:	retransfusion drain
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-08-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL27458.098.10