A prospective, randomized, controlled trial of retransfusion of intra-operatively collected filtered whole blood in total hip surgery.

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The purpose of this study is to document the efficacy, measured by allogeneic blood transfusion rate, of the Sangvia® Blood Management System when used for intra-operative, and if bleeding continues after surgery, possibly also postoperative...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Interventional

Summary

ID

NL-OMON33014

Source
ToetsingOnline

Brief title
Sangvia in total hip replacement

Condition

- Therapeutic procedures and supportive care NEC

Synonym
retransfusion of autologous blood, Sangvia Blood Management System

Research involving
Human

Sponsors and support

Primary sponsor: AstraTech AB

Source(s) of monetary or material Support: sponsor: AstraTech

Intervention

Keyword: allogeneic transfusion, intraoperative autotransfusion system, total hip replacement

Outcome measures

Primary outcome

- Frequency and amount of allogeneic blood transfusion

Secondary outcome

- Post-operative infection rate (SIRS reaction, clinical symptoms, wound

infection, CRP and LPC)

- Post-operative antibiotic use

- Length of hospital stay

- Post-operative haemoglobin concentration

- Demographical data (e.g. vital signs, age, gender etc)

- Health status questionnaire (i.e. EQ-5D)

Study description

Background summary

Transfusion of postoperative autologous blood has been found to reduce the need for allogeneic
blood transfusion and also reduce the number of postoperative infections. Publications
on the effect of intraoperative filtrated whole blood collection and transfusion are however today
very limited or non-existing. The purpose of this study is to document the efficacy, measured by
allogeneic blood transfusion rate, of the Sangvia® Blood Management System when used for
intra-operative, and if bleeding continues after surgery, possibly also

postoperative autologous
whole blood transfusion in total hip replacement surgery. The study will also add safety data to
previously reported studies.

Study objective

The purpose of this study is to document the efficacy, measured by allogeneic blood transfusion rate, of the Sangvia® Blood Management System when used for intra-operative, and if bleeding continues after surgery, possibly also postoperative autologous whole blood transfusion in total hip replacement surgery. The study will also add safety data to
previously reported studies.

Study design

The study is an assessor blind, prospective, randomized, controlled, multi-centre investigation of
300 patients. Patients will be followed during their hospital stay and at 2 months after discharge.

Intervention

Intra-operative, and if bleeding continues after surgery, possibly also post-operative autologous
blood transfusion with the Sangvia® system (test group).

Study burden and risks

Patients will as much as possible be followed during hospital stay and at routine follow-up. The extra blood samples taken from the patient can also be combined with standard hospital policy.

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

- provision of informed consent
- scheduled for primary or secondary, cemented or non-cemented, total hip arthroplasty
- ASA classification I-III

Exclusion criteria

- current symptoms of haemophilia
- current symptoms of hyperkalaemia
- current symptoms of impaired renal function (normal reference level)
- current untreated anaemia (Hb level < 7 mmo/L)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-06-2009
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	Sangvia blood salvage system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-03-2009
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
ClinicalTrials.gov	NCT00822588
CCMO	NL26575.098.09