An open, randomised, single center study to compare a low suction intra and postoperative autologous blood transfusion system with no drainsystem at all with regards to haemoglobin loss following primary total hip arthroplasty implantation

Published: 09-04-2009
Last updated: 05-05-2024

for summary see the dutch version above

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

Summary

ID

NL-OMON32927

Source
ToetsingOnline

Brief title
Comparison of a bloodtransfusion system with no drain, during hipsurgery

Condition

- Joint disorders

Synonym
hip replacement operation, total hip arthroplasty

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: niet van toepassing

Intervention

Keyword: autologous, drainage, hip prosthesis, transfusion

Outcome measures

Primary outcome

for summary see the dutch version above

Secondary outcome

for summary see the dutch version above

Study description

Background summary

for summary see the dutch version above

Study objective

for summary see the dutch version above

Study design

for summary see the dutch version above

Intervention

for summary see the dutch version above

Study burden and risks

for summary see the dutch version above

Contacts

Public
Isala Klinieken

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8011 RW
NL
Scientific
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8011 RW
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

age 18 years and up
provision of written informed consent
the patient is subject to a total hip arthroplasty implantation

Exclusion criteria

coagulation disorders, including thrombo embolic history
malignancy
ongoing infections
untreated hypertension
renal dysfunction

unstable angina pectoris
myocardial infarction within the past 12 months
bypass-operation within the past 12 months
intake of anticoagulants
participation in other clinical trials dealing with any drugs which influences blood loss

Study design

Design

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):	03-08-2009
Enrollment:	214
Type:	Actual

Medical products/devices used

Generic name:	intra and postoperative autologous blood transfusion system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-04-2009
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL27172.075.09