De-implementation of non cost-effective blood saving measures in total hip and knee replacement

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27165

Source
Nationaal Trial Register

Brief title
LISBOA

Health condition

implementation, blood management, total hip arthroplasty, total knee arthroplasty, behavior change
implementatie, bloed management, totale heup arthroplastiek, totale knie arthroplastiek, gedragsverandering

Sponsors and support

Primary sponsor: Leiden University Medical Center
P.O. Box 9600, 2300 RC Leiden, the Netherlands
Source(s) of monetary or material Support: - Netherlands Organisation for Health Research and Development (ZON-MW)
- Jon J van Rood, Netherlands Center for Clinical Transfusion Research (Sanquin)

Intervention

Outcome measures

Primary outcome

The primary outcome is the % of patients undergoing primary elective total hip or knee arthroplasty in which EPO or blood salvage is applied.

Secondary outcome

Secondary study parameters are the patient outcomes of the surgery including post-operative hemoglobin (Hb) level, length of hospital stay and number of allogeneic transfusions. Also possible complications will be registered: reactions on EPO use, transfusion reactions due to the use of blood salvage, transfusion reactions due to allogeneic transfusions, other (serious) adverse events.

Study description

Background summary

Hospital-clustered RCT comparing a tailored de-implementation intervention with no intervention in 20 hospitals to change the blood management behavior of orthopedic surgeons and anesthesiologists.

Study objective

This study aims to change the blood management behavior of orthopedic surgeons and anesthesiologists in primary elective total hip and knee arthroplasties, using a tailored intervention strategy for de-implementation of EPO and blood salvage.

The hypothesis is that the intervention results in an absolute decrease of 20% in patients receiving EPO or blood salvage in comparison to usual care (control intervention).

Study design

Because the alternative study design, the measurement points are not patient-related but predetermined.
The measurement points are: 1st August to 31 December 2013 baseline. October 1st 2014 to February 28th 2015 follow-up.
The months in between: January 1, 2014 to September 30, 2014 form the intervention period.

Intervention

- Interactive education aimed at orthopedic surgeons and anesthesiologists

- Feedback in an educational outreach visit aimed at orthopedic surgeons and anesthesiologists

- Dissemination and reports on hospital performance/ best practices aimed at orthopedic surgeons and anesthesiologists

- Information letter/ email aimed at other involved professionals (transfusion committee, OR-personnel, pharmacists).

Contacts

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Eligibility criteria

Inclusion criteria

- Hospitals using EPO and/or blood salvage in patients undergoing primary elective THA or TKA on a regular basis (more frequently than in exceptional cases)

- Hospitals performing at least 50 THA and/or TKA on average per 5 months.

Exclusion criteria

- Hospitals considering to abandon the use of EPO or blood salvage on their own initiative

- Hospitals participating in trials that interfere with the use or the discontinuation of EPO or blood salvage

- Hospitals employing the same group of orthopaedic surgeons or anaesthesiologists as a previous included hospital.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2013
Enrollment:	20
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL3883
NTR-old	NTR4044
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A