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Optimal blood management in elective orthopaedic surgery: the Transfusion "Op Maat" (TOMaat) study

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/01/2021	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
NCT00998088

Protocol serial number
NTR303; ZonMW: 945-06-601

Study information

Scientific Title
Optimal blood management in elective orthopaedic surgery: the Transfusion "Op Maat" (TOMaat) study

Acronym
TOMaat

Study objectives
Does the use of alternatives to allogeneic blood (erythropoietin or reinfusion of autologous shed blood intra- and/or post-operatively) for patients undergoing elective total knee- or hip replacement surgery lead to continuous sparing of allogeneic blood if a restrictive transfusion policy is in operation?

As of 05/06/2009 this record has been updated to include an amended anticipated end date; the initial end date at the time of registration was 31/12/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Primary study design
Interventional

Study design
Multicentre randomised active controlled parallel group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Total Knee Replacement (TKR)/Total Hip Replacement (THR)

Interventions
Stratification depending on the pre-operative Hemoglobin (Hb) level:
Stratum I: Hb greater than 6.1 mmol/L or less than 8.2 mmol/L (eligible for Epo randomisation)
Stratum II: Hb less than 6.2 mmol/L or greater than 8.1 mmol/L (not eligible for Epo)

Patients in both strata will be sequentially randomised for:
1. No use of autologous wound-drained blood (control group)
2. Post-operative retransfusion of wound-drained blood, or
3. Peri-operative use of the cell saver with post-operative retransfusion of wound-drained blood

Enrolment for this trial was completed on 31/10/2008.

Intervention Type
Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)
Number of red blood cell (RBC) transfusions in the following blood management strategies:
1. Comparison of Epo versus no Epo
2. Comparison of cell saver versus no cell saver
3. Comparison of drain system versus no drain system, independent of cell saver

Key secondary outcome(s)
1. Post-operative complications
2. Length of hospital stay (LOHS)
3. Post-operative Hb/haematocrit (Hct)
4. Rehabilitation time
5. Mobility and functional abilities of knee-or hip
6. Quality of life scores
7. Costs analysis

Completion date
01/10/2009

Eligibility

Key inclusion criteria
All orthopedic patients of 18 years and older being considered for a primary or revision total knee replacement (TKR) or total hip replacement (THR).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
3689

Key exclusion criteria
1. Refusal of allogeneic blood
2. Pregnancy
3. Patients with uncontrolled hypertension
3. Cardiac instability
4. Recent CVA

5. Symptomatic atherosclerosis
6. Sickle cell anaemia
7. Cancer in the wound area
8. Unsuitability for peri-operative anticoagulation prophylaxis
9. Known allergy to erythropoietin
10. Infected prosthesis or wound

Date of first enrolment
01/05/2004

Date of final enrolment
01/10/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Sanquin Bloodbank ZW
Leiden
Netherlands
2333 BZ

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Funder Name
Roche Nederland BV (Netherlands)

Funder Name
Haemonetics BV (Netherlands)

Funder Name
Sanquin Bloodbank Amsterdam (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/09/2020	26/01/2021	Yes	No