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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
20/12/2005		☐ 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	Surgerv			

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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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

#### Study design

Multicentre randomised active controlled parallel group trial

#### Primary study design

Interventional

#### 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