Optimal blood management in elective orthopaedic surgery. The Transfusion "Op Maat" (TOMaat) study.

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Does the use of alternatives to allogeneic blood (erythropoietin or reinfusion of autologous shed blood intra- and/or postoperatively) for patients undergoing elective total knee- or hip replacement surgery lead to continuous sparing of allogeneic...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24569

Bron
Nationaal Trial Register

Verkorte titel
TOMaat study.

Aandoening

Primary and revision total knee (TKR)-and hip replacement (THR) surgery patients.

Ondersteuning

Primaire sponsor: LUMC, department of Orthopaedics
Overige ondersteuning: ZonMW projectnumber: 945-06-601

Sanquin Bloodbank, Amsterdam, NL Projectnr. PPOC 03-002.

Roche Nederland BV, Mijdrecht, NL

Haemonetics BV Breda, NL

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective/research questions:
What is the optimal transfusion management in elective orthopaedic surgery patients and what are the related costs?

Study design/intervention(s): a prospective, double randomised, open, multicenter study in which patients are stratified according to their preoperative hemoglobin(Hb) level: stratum I= Hb between 6,1 and 8,2 mmol/l. These patients are first randomised for Erythropoietin (Epo)or no Epo.
Stratum II= Hb of 6,1 and lower or 8,2 mmol/l and higher, are not eligible for Epo and thus not randomised. Patients in both strata will be randomised for three modalities: a cell saver (to wash, filter and reinfuse autologous shed blood) which is used intra- and postoperatively or a postoperative autologous reinfusion drainage system only (to filter and reinfuse autologous shed blood) or a restrictive transfusion trigger only (controls).

Study population/datasets: primary and revision total knee (TKR)-and hip replacement (THR) surgery patients.

Outcome measures:
Primary outcome: number of allogeneic red blood cell (RBC) transfusions.
Hypotheses:
1. comparison of Epo versus no Epo;
2. comparison of cell saver versus no cell saver;
3. comparison of drain versus no drain Secondary outcome:
1. postoperative complications;
2. length of hospital stay (LOHS);
3. postoperative Hb;
4. Quality of life;
5. functional Hip-,or Knee- scores;
6. rehabilitation;

7. costs analysis.

Power/data analysis: In order to be able to detect a 75% reduction of allogeneic transfusions by Epo and a reduction of 30% by autologous (shed blood) transfusions (cell saver or postoperative drain) with a power= 0.9 and an alpha= 0.05, inclusion of 2250 surgery patients (in a worst case scenario of high standard deviations) are required for intention-to-treat analysis.

Economic evaluation: analysis of short-term direct medical costs, including bloodproducts, Epo, cell saver, postoperative autologous blood reinfusion drain systems.

Doel van het onderzoek

Does the use of alternatives to allogeneic blood (erythropoietin or reinfusion of autologous shed blood intra- and/or postoperatively) 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?

Onderzoeksproduct en/of interventie

Stratification depending on the pre-operative Hemoglobin (Hb) level:
Stratum I: 6,1 mmol/L < Hb < 8,2 mmol /L (eligible for Epo randomisation)
Stratum II: Hb < 6,2 mmol/L or >8,1 mmol/L (not eligible for Epo).
Patients in both strata will be sequentially randomised for:
a. no use of autologous wound-drained blood (control group)
b. post-operative retransfusion of wound-drained blood or
c. peri-operative use of the cell saver with post-operative retransfusion of wound-drained blood.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Refusal of allogeneic blood, pregnancy, patients with uncontrolled hypertension, cardiac instability, recent CVA, symptomatic atherosclerosis, sickle cell anaemia, cancer in the wound area , unsuitability for peri-operative anticoagulation prophylaxis, known allergy to erythropoietin and patients with an infected prosthesis or wound.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2004

Aantal proefpersonen:	2250
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL265
NTR-old	NTR303
Ander register	: ZonMW projectnumber: 945-06-601
ISRCTN	ISRCTN96327523

Resultaten

Samenvatting resultaten
N/A