“The effect of duration of wound drainage on allogeneic blood transfusions using a postoperative retransfusion system after major orthopaedic surgery.”

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A postoperative retransfusion system is most effective in terms of allogeneic blood transfusion rates when in situ for maximum of 6 hours after major orthopaedic surgery.

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

Samenvatting

ID

NL-OMON26356

Bron
NTR

Verkorte titel
Drain duration in joint replacement

Aandoening

retransfusion, retransfusie
drain
joint arthroplasty, gewrichtsvervanging
duration, tijd

Ondersteuning

Primaire sponsor: MC Haaglanden
Locatie Antoniushove en Westeinde
Postbus 432
2501 CK Den Haag

Overige ondersteuning: no

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Allogeneic blood transfusion rate.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Use of post operative wound drains in hip and knee arthroplasty is still debated. Drainage is said to reduce wound haematoma, improves wound healing and prevents infection. Therefore many patients are treated with wound drainage until the first postoperative day. However, it is also said that continual drainage after surgery will increase the amount of shed blood because the counteraction of haematoma formation will not take place. In addition, drains may act as access route for bacterial contamination of the wound which can cause a periprosthetic infection. This favours no drainage at all. These assumptions are based on results in patients where a drain was used as a drainage system only. However, retransfusion drainage systems after arthroplasty are gaining popularity. These retransfusion systems are used to reduce the need for allogeneic blood transfusions. It is interesting if the potential benefits outweigh the controversial thoughts in drainage. Therefore we want to evaluate whether drainage, using a retransfusion system, after major arthroplasty is useful at all.

Objective:

Is the use of postoperative autologous retransfusion drainage (ARD) systems useful in hip and knee arthroplasty.

Study design:

After inclusion, patients are randomised into three groups. Group 1: no drainage, group 2: drainage for 6 hours after surgery and group 3: drainage for 24 hours after surgery. Randomisation with sealed envelopes (stratification per clinic) will be done at the end of

surgery just before wound closure. Shed blood in group 2 and 3 is collected and retransfused 6 hours after surgery. After retransfusion the drain is removed in group 2 whereas the drain is continued for drainage until drain removal the first postoperative morning.

Study population:

570 patients planned to undergo primary total hip and knee arthroplasty fulfilling the in- and exclusion criteria will enter this study after given written informed consent.

Intervention:

An existing intervention will be investigated, autologous retransfusion drainage with the Bellovac® ABT retransfusion system.

Main study parameters/endpoints:

The primary endpoint is the amount of allogeneic blood transfusions in the three groups. Allogeneic blood transfusions are given by specific haemoglobin levels. Secondary endpoints are haemoglobin levels in the perioperative period, and complications with special focus on wound healing disturbances after surgery. Furthermore, all clinical data will be collected such as length of hospitalisation, co morbidity and others.

Nature and extent of the burden and risks associated with participation benefit and group relatedness:

There are no potential risks or benefits related to participation in this study.

Doel van het onderzoek

A postoperative retransfusion system is most effective in terms of allogeneic blood transfusion rates when in situ for maximum of 6 hours after major orthopaedic surgery.

Onderzoeksopzet

1. Pre-operative;

2. Day 1;

3. Day 3;

4. 6 weeks.

Onderzoeksproduct en/of interventie

Autologous retransfusion drainage with the Bellovac® ABT retransfusion system.

After inclusion, patients are randomised into three groups:

1. Group 1: No drainage;

2. Group 2: Drainage for 6 hours after surgery;

3. Group 3: Drainage for 24 hours after surgery.

Randomisation with sealed envelopes (stratification per clinic) will be done at the end of surgery just before wound closure. Shed blood in group 2 and 3 is collected and retransfused 6 hours after surgery. After retransfusion the drain is removed in group 2 whereas the drain is continued for drainage until drain removal the first postoperative morning.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients scheduled to undergo elective major orthopaedic surgery (hip, knee);

2. Male and non-pregnant female patients between 18-80 years of age;

3. The individual is physically and mentally willing and able to comply with postoperative functional evaluation and able to participate in an appropriate rehabilitation schedule;

4. Patients who signed the Ethics Committee approved specific Informed Consent Form prior to surgery.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with a major surgical procedure during the 12 weeks before the study-related operation;

2. No other used alternatives to reduce allogeneic blood transfusions, such as preoperative epoetin alpha (Eprex®) injections or intra-operative cell saving (Sangvia®);

3. Clinical or laboratory evidence of untreated iron, folate or vitamin B12 deficiency;

4. Recent Myocardial Infarction or CVA (<3 months);

5. Dutch language not mastered;

6. The patient is pregnant or planning a pregnancy after surgery (or is using inadequate birth control);

7. Mentally disabled patients;

8. Current malignancy or any active infection.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2010
Aantal proefpersonen:	570
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2010
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	NL2394

Register	ID
NTR-old	NTR2501
Ander register	METC MC Haaglanden : 10-069
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A