# Reduction of allogenic blood transfusion and increased activation of coagulation by reinfusion of post-operative autologous wound blood in patients undergoing total knee and total hip replacement

Submission date 10/10/2011	<b>Recruitment status</b> No longer recruiting	Prospectively registered
		[_] Protocol
<b>Registration date</b> 12/03/2012	<b>Overall study status</b> Completed	[] Statistical analysis plan
		[_] Results
Last Edited	Condition category	Individual participant data
19/05/2015	Musculoskeletal Diseases	[] Record updated in last year

### Plain English summary of protocol

Background and study aims

During an operation to replace your hip or knee there is often considerable blood loss. It is possible to collect your own blood from the wound area and return it to you by re-infusion within 6 hours after the operation. This might reduce the number of blood transfusions that you may need after this kind of operation. However, this has never been proven. In addition, it is also not known if re-infusion of wound blood is completely safe. Theoretically, re-infusion of wound blood might lead to activation of your coagulation (clotting) system and therefore to an increased risk of thrombosis (blood clots). Therefore this study will investigate whether re-infusion of wound blood leads to an reduction of blood transfusion, and whether re-infusion of the coagulation system and to an increased risk of thrombosis.

#### Who can participate?

Patients aged 18 or older who need a hip or knee replacement.

#### What does the study involve?

Participants will be divided into two groups: one group will receive their own wound blood within 6 hours after the operation, whereas the other group will not. After the study has finished the number of blood transfusions will be compared between the two groups of patients. A number of laboratory coagulation tests will be carried out and the number of patients who have developed thrombosis will be compared between the two groups.

#### What are the possible benefits and risks of participating?

Several hospitals in the Netherlands that perform knee and hip replacement operations already use the practice of re-infusion of the patients own wound blood. The Medical Ethical Committee therefore concluded that there is no increased risk for participants.

Where is the study run from? Maxima Medical Centre, Eindhoven, the Netherlands.

When is the study starting and how long is it expected to run for? The study took place from May 2004 to February 2006.

Who is funding the study? Maxima Medical Centre, Eindhoven, the Netherlands.

Who is the main contact? Dr Arnold T. Besselaar

### **Contact information**

**Type(s)** Scientific

**Contact name** Dr Arnold T. Besselaar

**Contact details** Michelangelolaan 2 Eindhoven Netherlands 5653EJ

### Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 0419

### Study information

#### Scientific Title

A randomized controlled double-blind observational trial of re-infusion of post-operative, autologous wound blood in patients undergoing total knee or hip arthroplasty: efficacy (reduction of allogenic blood transfusion) and activation of coagulation (increased coagulation activation in comparison to control group)

#### **Study objectives**

The principle questions of the study are: 1. Can the number of allogenic blood transfusions in orthopaedic patients, be reduced by post operatively re-infused autologous wound blood 2. Does reinfusion of post-operative autologous wound blood lead to increased activation of coagulation in orthopaedic patients undergoing total hip or knee replacement

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** The Medical Ethical Board of the Maxima Medical Centre Eindhoven, 15/04/2004, ref: 0419

**Study design** Randomised double-blind controlled observational single-centre study

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### Health condition(s) or problem(s) studied

Degenerative arthritis in hip or knee

#### Interventions

Pre and at various post operative timepoints blood samples are taken for analysis of several haematological and coagulation parameters [e.g. haemoglobin (Hb), leucocytes, prothrombin time (PT), activated partial thromboplastin time (APTT) and coagulation activation parameters such as thrombin-antithrombin III complexes (TAT), prothrombin fragment (PF) 1+2 and d-dimers]. The numbers of allogenic blood transfusions is registred according to a strict transfusion protocol. In addition 2 weeks post operatively a colour duplex sonography is performed.

#### Intervention Type

Procedure/Surgery

#### Primary outcome measure

 Hb, APTT, PT, Fibrinogen, TAT, PF 1 + 2 and d-dimer are measured in blood samples taken 12 hours pre operatively and at 3 hours postoperatively and 1 and 4 hours after re-infusion of autologous wound blood and at 24 hours, 14 days, 6 weeks and 3 months post operatively.
The number of allogenic blood tranfusions is registred. Allogenic bloodtransfusion is given according to a strictly handled tranfusion protocol

3. Two weeks post operatively a colour duplex sonography is performed

#### Secondary outcome measures

1. Number of post-operative transfusion reactions

2. Number of secondary wound infections

**Overall study start date** 12/05/2004

Completion date 01/02/2006

## Eligibility

#### Key inclusion criteria

Patients aged 18 years or older
An indication exists for total knee or hip replacement

Participant type(s) Patient

**Age group** Adult

**Lower age limit** 18 Years

**Sex** Both

**Target number of participants** 130

#### Key exclusion criteria

- 1. Who were using coumarin derivates or heparin
- 2. Suffering from malignancies or with a history of malignancy within the previous 5 years
- 3. With a history of venous thromboembolic disease
- 4. Indicated for revision surgery
- 5. With less than 100ml collected autologous wound blood

Date of first enrolment

12/05/2004

**Date of final enrolment** 01/02/2006

### Locations

**Countries of recruitment** Netherlands **Study participating centre Michelangelolaan 2** Eindhoven Netherlands 5653EJ

### Sponsor information

**Organisation** Maxima Medical Centre (Netherlands)

**Sponsor details** Postbus 7777 Veldhoven Netherlands 5500MB

**Sponsor type** Hospital/treatment centre

Website http://www.mmc.nl/

ROR https://ror.org/02x6rcb77

### Funder(s)

Funder type Hospital/treatment centre

**Funder Name** Maxima Medical Centre Eindhoven - Local Scientific Foundation (Netherlands)

### **Results and Publications**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

**IPD sharing plan summary** Not provided at time of registration