

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/03/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 19/05/2015	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 wound blood leads to activation 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

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## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

1. 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.
2. 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

## **Key secondary outcome(s)**

1. Number of post-operative transfusion reactions
2. Number of secondary wound infections

## **Completion date**

01/02/2006

## **Eligibility**

### **Key inclusion criteria**

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

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Who were using coumarin derivatives 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**

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Eindhoven

Netherlands

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**Sponsor information****Organisation**

Maxima Medical Centre (Netherlands)

**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**

### **Individual participant data (IPD) sharing plan**

#### **IPD sharing plan summary**

Not provided at time of registration