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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

Submission date
10/10/2011

Recruitment status
No longer recruiting

Registration date
12/03/2012

Overall study status
Completed

Last Edited
19/05/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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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
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

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
1. Patients aged 18 years or older
2. 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