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The clinical effects of leukocyte removal filters, cell savers and their combination on blood transfusion and organ damage during cardiac surgery

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
07/01/2019

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR244

Study information

Scientific Title
The clinical effects of leukocyte removal filters, cell savers and their combination on blood transfusion and organ damage during cardiac surgery

Acronym
filterstudie

Study objectives
We hypothesise that the application of a leukocyte depletion filter for surgical wound blood will reduce organ damage and coagulation disorders through removal of activated leukocytes and other particles.

We expect that the efficacy of a cell saver combined with a leukocyte filter increases by reduction of allogenic blood transfusions and organ damage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre randomised unblinded active-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
transfusion complications, organ damage, coagulation disorders

Interventions

The patients will be divided in 4 groups according to a randomisation table:
1. In group I (n = 150) blood will be processed with a cell saver and transfused without leukocyte removal filter
2. In group II (n = 150) blood will be processed with a cell saver and transfused through a leukocyte removal filter
3. In group III (n = 150) blood will be filtered with a leukocyte removal filter, but not be processed with a cell saver. The surgical wound suction blood before, during and after cardiopulmonary bypass and the residual heart lung machine blood will be collected in a separate cardiotomy reservoir and filtered with a leukocyte removal filter.
4. In group IV (n = 150) blood will be transfused without filter and without cell saver. The wound suction blood before and after cardiopulmonary bypass will be discarded, which is at this moment routine practice. The wound suction blood during cardiopulmonary bypass and the residual blood from the heart lung machine will be transfused unfiltered, which is at this moment routine practice.

In group I and II all the wound suction blood during the operation will be transferred to the cell saver instead of being wasted or returned to the heart lung machine as usual. In addition, the residual heart lung machine blood will be processed by the cell saver instead of being unprocessed transfused to the patient as usual.

Intervention Type
Device

Primary outcome measure
The number of allogenic blood products used.

Secondary outcome measures
1. Length of stay in the intensive care unit and in the hospital
2. Number of rethoracotomies (any re-exploration within 48 hours after the initial operation)
3. Myocardial infarction (new Q-wave on the electrocardiogram [ECG] and creatine kinase [CK] greater than 180 U/l with creatine kinase myocardial bands [CK-MB] greater than 10% of total)
4. Renal (serum creatinine greater than 1.5 baseline) and pulmonary dysfunction
5. Peri-operative infections
6. Costs of the interventions
7. Coagulation disorders
8. Markers of inflammation (leukocyte and granulocyte counts, interleukin-6, elastase, C-reactive protein, myeloperoxidase)

Overall study start date
01/12/2004

Completion date
01/06/2005

Eligibility

Key inclusion criteria
1. Adult patients scheduled for cardiac surgery
2. Informed consent

The study is not blinded, because intraoperative cell saving cannot be concealed by the size and noise of the apparatus. Blockwise randomisation will be employed to avoid imbalance. Numbered, sealed randomisation envelopes will be used. Randomisation will be registered centrally. The randomisation code will not be revealed to any of the participating investigators.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
650

Key exclusion criteria
1. Patients with known coagulation disorders except from the use of aspirin or low molecular weight heparin given at least 10 hours before surgery
2. Patients under 18 years
3. Patients presenting for emergency operations

Date of first enrolment
01/12/2004

Date of final enrolment
01/06/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Universitair Medisch Centrum Groningen
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Centre Groningen (UMCG) (The Netherlands)

Sponsor details
Department of General Practice
Hanzeplein 1
Groningen
Netherlands
9713 GZ

Sponsor type
Hospital/treatment centre

Website
http://www.umcg.nl/azg/nl/

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2015		Yes	No
Results article	results	01/03/2019		Yes	No