

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

☐ Prospectively registered

☐ Protocol

Registration date

20/12/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

07/01/2019

Condition category

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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