ISRCTN45666086 https://doi.org/10.1186/ISRCTN45666086

Leiden-Alloimmunisation-Likelihood (LAL) trial: alloimmunisation after pre-storage filtered, post-storage filtered and buffy-coat-depleted blood transfusion in cardiac surgery patients

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
23/10/2007

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr L.M.G. van de Watering

Contact details
Sanquin Blood Bank
Southwest region
Plesmanlaan 1a
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

n/a

Study information

Scientific Title

Acronym
LAL trial

Study objectives
The use of by filtration-leukocyte reduced blood transfusions in patients undergoing cardiac surgery, will result in lower alloimmunisation frequencies compared to using buffy-coat depleted blood transfusions. This has previously been shown in frequently transfused patients that received transfusions over a longer period of time, and is now investigated in patients receiving several units of blood around a single event, cardiac surgery. Also being investigated in this study is whether post-storage filtration is as effective as pre-storage filtration.

Ethics approval required
Old ethics approval format

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

Study design
Randomised, double blinded, 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
Blood transfusions in cardiac surgery

Interventions
Use of by filtration leukocyte reduced blood transfusions versus use of buffy-coat depleted blood transfusions (=1990's standard in NL).

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Anti-Human Leukocyte Antigen (HLA) antibody formation (tested by LCT) and anti-erythrocyte antibody formation (tested in 3 cell panel, with PEG). Samples for analyses are collected before surgery, on day 7 post-surgery, 3 - 10 weeks post-surgery and 20 - 30 weeks post-surgery.

Secondary outcome measures
1. Post-operative infections
2. Hospital stay
3. Intensive Care Unit (ICU)-stay
4. Mortality
5. Costs-effect-analyses
6. In combination with other Randomised Controlled Trials (RCTs), that have randomised between these same two blood products: long term effects on the incidence of autoimmune diseases and malignancies

Overall study start date
01/03/1992

Completion date
15/08/1994

Eligibility

Key inclusion criteria
Patients planned for open heart surgery: Coronary Artery Bypass Graft (CABG), heart valve surgery or the combination of both.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
944

Key exclusion criteria
1. Aged less than 18 years
2. Transfusions within last 6 months
3. Pre-existing medical indication for filtered blood products

Date of first enrolment
01/03/1992

Date of final enrolment
15/08/1994

Locations

Countries of recruitment
Netherlands

Study participating centre
Sanquin Blood Bank
Leiden
Netherlands
2333 BZ

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

Sponsor details
Albinusdreef 2
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
University/education

Website
http://www.lumc.nl/

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Industry

Funder Name
Red Cross Blood Bank Leidsenhage (The Netherlands)

Funder Name
NPBI International B.V. (The 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?
Other publications		01/07/1990		Yes	No
Other publications		17/02/1998		Yes	No
Other publications		01/01/2003		Yes	No