

Effects of transfusion of leucocyte-depleted erythrocytes in cardiac valve surgery on postoperative complications

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/11/2022	Condition category Surgery	<input type="checkbox"/> 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

Protocol serial number
N/A

Study information

Scientific Title

Effects of transfusion of leucocyte-depleted erythrocytes in cardiac valve surgery on postoperative complications

Study objectives

To investigate the role and mechanisms of leukocytes in allogeneic erythrocyte concentrates on postoperative complications, as Multiple Organ Dysfunction Syndrome (MODS), infections and death.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre, randomised, double blinded, active controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Heart surgery

Interventions

Randomisation to receive buffy-coat-depleted (PC) or leukocyte-depleted transfusions when necessary. Pre-operative, at arrival at Intensive Care Unit (ICU) and day 1 postoperatively at ICU blood samples were obtained.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

90-days mortality and causes of deaths.

Key secondary outcome(s))

1. In-hospital mortality
2. 30- and 60-days mortality
3. Onset and type of postoperative infections
4. Onset and type of MODS
5. ICU-stay, hospital-stay and long-term survival
6. Pro-and anti-inflammatory cytokine profile, complement system activation and inflammatory mediators
7. Cost-effective-analysis for the primary outcome

Completion date

01/05/2001

Eligibility

Key inclusion criteria

Patients undergoing valve surgery (+/- Coronary Artery Bypass Grafting [CABG]).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

496

Key exclusion criteria

1. Patients under 18 years of age
2. Medical indications for leucocyte-depleted erythrocytes
3. Received blood transfusions within previous 3 months

Date of first enrolment

01/05/1999

Date of final enrolment

01/05/2001

Locations

Countries of recruitment

Netherlands

Study participating centre

Sanquin Blood Bank

Leiden

Netherlands

2333 BZ

Sponsor information

Organisation

Netherlands Heart Foundation (Nederlandse Hartstichting) (Netherlands)

ROR

<https://ror.org/05nxhgm70>

Funder(s)**Funder type**

Charity

Funder Name

Netherlands Heart Foundation (The Netherlands) (grant ref: 98.183)

Results and Publications**Individual participant data (IPD) sharing plan**

Not provided at time of registration

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		08/06/2004		Yes	No
Other publications		01/06/2005		Yes	No