ISRCTN68522192 https://doi.org/10.1186/ISRCTN68522192

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

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 14/11/2022	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Y.M. Bilgin

Contact details
Sanquin Blood Bank
Department of Research and Education
Plesmanlaan 1a
Leiden
Netherlands
2333 BZ
+31 (0)71 568 5053
bilginyavuz@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Effects of transfusion of leucocyte-depleted erythrocytes in cardiac valve surgey 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
90-days mortality and causes of deaths.

Secondary outcome measures
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

Overall study start date
01/05/1999

Completion date
01/05/2001

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
496

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)

Sponsor details
P.O. Box 300
Den Haag
Netherlands
2501 CH
+31 (0)70 315 5555
info@hartstichting.nl

Sponsor type
Charity

Website
http://www.hartstichting.nl/go/

ROR
https://ror.org/05nxhgm70

Funder(s)

Funder type
Charity

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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