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

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

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