

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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25360

Source

Nationaal Trial Register

Brief title

N/A

Health condition

Cardiac valve surgery +/- CABG.

Sponsors and support

Primary sponsor: Dutch Heart Foundation, No 98.183.

Intervention

Outcome measures

Primary outcome

90-days mortality and causes of deaths.

Secondary outcome

1. In-hospital mortality, 30- and 60-days mortality, onset and type of postoperative infections, onset and type of multiple-organ-dysfunction-syndrome (MODS), ICU-stay, hospital-stay and long-term survival. Pro-and anti-inflammatory cytokine profile, complement system activation and inflammatory mediators.
2. Cost-effective-analysis for the primary outcome.

Study description

Background summary

The primary outcome and some secondary outcomes are published. The analysis of blood samples are still continuing and the long-term analysis is still ongoing.

Study objective

To investigate the role and mechanisms of leukocytes in allogeneic erythrocyte concentrates on postoperative complications, as MODS, infections and death.

Study design

N/A

Intervention

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

Contacts

Public

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Eligibility criteria

Inclusion criteria

Patients undergoing valve surgery (+/- CABG).

Exclusion criteria

Patients under 18 years of age, patients with medical indications for leucocyte-depleted erythrocytes and who received blood transfusions within previous 3 months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-1999
Enrollment:	496
Type:	Actual

Ethics review

Positive opinion

Date: 10-09-2005

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL298
NTR-old	NTR336
Other	: N/A
ISRCTN	ISRCTN68522192

Study results

Summary results

Circulation. 2004 Jun 8;109(22):2755-60.

Transfus Med. 2005 Jun;15(3):209-17.