Transfusion induced complications = transfusion associated complications ? study.

No registrations found.

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

Summary

ID

NL-OMON21130

Source
NTR

Brief title
TACTICS

Health condition

The study population exists of major, non-cardiac surgery patients, who are expected to need > 3 units of red blood cell transfusions.

Sponsors and support

Primary sponsor: LUMC financed by the Ziekenfondsraad/ZonMW
Source(s) of monetary or material Support: 1.OG 99/023 of the Ziekenfondsraad/ZonMW;

2. Sanquin Blood supply.

Intervention

Outcome measures

Primary outcome

Postoperative:

1. In-hospital mortality;

2. Duration of intensive care stay.

Secondary outcome

1. Postoperative multi organ failure;

2. Postoperative infections;

3. Length of hospital stay;

4. Costs/benefits of universal leukocyte depletion for the Dutch health care;

5. Role of perioperative medication;

Follow up

1. Long term survival;

2. Cancer recurrence in GI patients;

3. Predictive role of cytokines and related genes.

Study description

Background summary

The aim of the study is to compare postoperative complications in patients undergoing major surgery who received non-filtered or filtered red blood cell transfusions.

No significant differences were found in mortality (odds ratio for filtered v non-filtered 0.80, 95% confidence interval 0.53 to 1.21) and in mean stay in intensive care (- 0.4 day, - 1.6 to 0.6 day). In the filtered group the mean length of hospital stay was 2.4 days shorter (- 4.8 to 0.0 day; P = 0.050) and the incidence of multi-organ failure was 30% lower (odds ratio 0.70, 0.49 to 1.00; P = 0.050).

There were no differences in rates of infection (0.98, 0.73 to 1.32).

Conclusion:

The use of filtered transfusions in some types of major surgery may reduce the length of hospital stay and the incidence of postoperative multi-organ failure.

Study objective

Does removal of allogeneic white blood cells by filtration reduce postoperative complications?

Study design

N/A

Intervention

Transfusions of filtered red blood cell concentrates vs. transfusion of stored buffy coat depleted red blood cell concentrates.

Contacts

Public
Sanquin Blood Supply Foundation,
P.O. Box 2184

J.A. Hilten, van
Leiden 2310 CD
The Netherlands
+31 (0)71 5685060
Scientific
Sanquin Blood Supply Foundation,
P.O. Box 2184

J.A. Hilten, van
Leiden 2310 CD
The Netherlands
+31 (0)71 5685060

Eligibility criteria

Inclusion criteria

Acute aneurysm-, elective aneurysm-, orthopaedic- and large gastro-intestinal surgery patients.

Exclusion criteria

1. Under 18 years of age;

2. Transfusions received within 3 months prior to inclusion;

3. Pre existing medical indication for filtered red blood cell transfusions.

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):	23-03-2000
Enrollment:	1548
Type:	Actual

Ethics review

Positive opinion

Date:	09-09-2005
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	NL271
NTR-old	NTR309
Other	: N/A
ISRCTN	ISRCTN48093674

Study results

Summary results
1. BMJ 2004; 328:1281-4
2. Ned Tijdschrift voor Hematologie 2005; 2:140-7