Transfusion induced complications = transfusion associated complications? study

Submission date 20/12/2005	Recruitment status No longer recruiting	Prospectively registered	
20/12/2005	No longer recruiting	Protocol	
Registration date	e Overall study status Completed	Statistical analysis plan	
20/12/2005		[X] Results	
Last Edited 04/12/2007	Condition category Signs and Symptoms	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers n/a

Study information

Scientific Title

The effects of leukocyte filtered versus buffy coat depleted erythocyte transfusions in major surgery patients

Acronym

TACTICS

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

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 Blood transfusions complications

Interventions

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

Intervention Type Other

Phase Not Specified

Primary outcome measure

Postoperative:

1. In-hospital mortality

2. Duration of intensive care stay

Secondary outcome measures

- 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

Overall study start date

23/03/2000

Completion date

31/12/2001

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Age group

Adult

Sex Both

Target number of participants 1548

Key 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

Date of first enrolment

23/03/2000

Date of final enrolment 31/12/2001

Locations

Countries of recruitment Netherlands

Study participating centre Sanquin Blood Supply Foundation Leiden Netherlands 2310 CD

Sponsor information

Organisation Leiden University Medical Centre (LUMC) (Netherlands)

Sponsor details Albinusdreef 2 P.O. Box 9600 Leiden Netherlands 2300 RC

Sponsor type University/education

Website http://www.lumc.nl/

ROR https://ror.org/027bh9e22

Funder(s)

Funder type Research organisation

Funder Name The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Funder Name

Sanquin Bloodbank Amsterdam (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	Results	29/05/2004		Yes	No