ISRCTN48093674 https://doi.org/10.1186/ISRCTN48093674

Transfusion induced complications = transfusion associated complications? study

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

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?
Results article	Results	29/05/2004		Yes	No