# Leiden-Alloimmunisation-Likelihood (LAL) trial: alloimmunisation after pre-storage filtered, post-storage filtered and buffy-coat-depleted blood transfusion in cardiac surgery patients

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  Condition category	Results	
Last Edited		Individual participant data	
23/10/2007	Surgery	Record updated in last yea	

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr L.M.G. van de Watering

#### Contact details

Sanquin Blood Bank Southwest region Plesmanlaan 1a Leiden Netherlands 2333 BZ

#### Additional identifiers

**Protocol serial number** n/a

# Study information

Scientific Title

#### Acronym

LAL trial

#### Study objectives

The use of by filtration-leukocyte reduced blood transfusions in patients undergoing cardiac surgery, will result in lower alloimmunisation frequencies compared to using buffy-coat depleted blood transfusions. This has previously been shown in frequently transfused patients that received transfusions over a longer period of time, and is now investigated in patients receiving several units of blood around a single event, cardiac surgery. Also being investigated in this study is whether post-storage filtration is as effective as pre-storage filtration.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval received from the local medical ethics committee

#### Study design

Randomised, double blinded, active controlled, parallel group trial.

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Blood transfusions in cardiac surgery

#### Interventions

Use of by filtration leukocyte reduced blood transfusions versus use of buffy-coat depleted blood transfusions (=1990's standard in NL).

#### Intervention Type

Procedure/Surgery

#### Phase

**Not Specified** 

#### Primary outcome(s)

Anti-Human Leukocyte Antigen (HLA) antibody formation (tested by LCT) and anti-erythrocyte antibody formation (tested in 3 cell panel, with PEG). Samples for analyses are collected before surgery, on day 7 post-surgery, 3 - 10 weeks post-surgery and 20 - 30 weeks post-surgery.

#### Key secondary outcome(s))

- 1. Post-operative infections
- 2. Hospital stav
- 3. Intensive Care Unit (ICU)-stay
- 4. Mortality

5. Costs-effect-analyses

6. In combination with other Randomised Controlled Trials (RCTs), that have randomised between these same two blood products: long term effects on the incidence of autoimmune diseases and malignancies

#### Completion date

15/08/1994

# **Eligibility**

#### Key inclusion criteria

Patients planned for open heart surgery: Coronary Artery Bypass Graft (CABG), heart valve surgery or the combination of both.

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Key exclusion criteria

- 1. Aged less than 18 years
- 2. Transfusions within last 6 months
- 3. Pre-existing medical indication for filtered blood products

#### Date of first enrolment

01/03/1992

#### Date of final enrolment

15/08/1994

# **Locations**

#### Countries of recruitment

Netherlands

# Study participating centre Sanquin Blood Bank

Leiden Netherlands 2333 BZ

# Sponsor information

#### Organisation

Leiden University Medical Centre (LUMC) (Netherlands)

#### **ROR**

https://ror.org/027bh9e22

# Funder(s)

### Funder type

Industry

#### **Funder Name**

Red Cross Blood Bank Leidsenhage (The Netherlands)

#### **Funder Name**

NPBI International B.V. (The Netherlands)

# **Results and Publications**

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?
Other publications		01/07/1990		Yes	No
Other publications		17/02/1998		Yes	No
Other publications		01/01/2003		Yes	No