Effect of peri-operative transfusion of blood products on pulmonary leakage measured with the pulmonary leakage index in a cohort of cardiac surgery patients.

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1) to determine whether blood transfusion leads to pulmonary leakage measured by PLI2)to determine if pulmonary leakage is correlated with: - the type of transfusion (erythrocytes, plasma or platelets) - the amount of transfusion - type of donor -...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON30813

Source
ToetsingOnline

Brief title
Effect of bloodtransfusion on PLI measurement

Condition

- Other condition

Synonym
Transfusion reaction

Health condition

Bloedtransfusie reacties

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ALI, PLI, TRALI, Transfusion

Outcome measures

Primary outcome

PLI

Secondary outcome

HLA/HNA typing of transfusion

Concentration of LysoPCs in transfusion material

Concentration of inflamation markers in the broncho alveolair lavage

Study description

Background summary

Cardiac surgery patients post operatively often have a compromised oxygenation. Many causes are suggested, e.g. atelectasis, pulmonary edema and acute lung injury (ALI) or its more severe form acute respiratory distress syndrome (ARDS). A possible important factor may be peri-operative blood transfusions causing transfusion related acute lung injury (TRALI). TRALI is thought to be a two hit entity. The *first hit* is lung endothelial activation with priming of the neutrophils in the lung, caused by e.g. an operation, trauma or an infection. The *second hit* is caused by the bloodtransfusion, resulting in neutrophil activation and finally pulmonary leakage. Either antibodies present in donor blood or bio-active lipids which accumulate during storage of blood account for the second hit. For several reasons, cardiac surgery patients may form a group of patients at high risk for TRALI. During the intra-thoracic surgical procedure the lungs are usually left deflated and non-ventilated for several hours, which may cause injury to the lung vasculature (the *primary

hit*). Secondly, these patients often receive transfusion of blood products. The distinction between hydrostatic pulmonary edema and ALI is difficult because of the low specificity of clinical diagnostic criteria. Furthermore, these entities may not be mutually exclusive. The Pulmonary Leak Index (PLI) can be used as a measure of microvascular permeabiltity and has been shown to be an early marker of acute lung injury in critically ill patients. The PLI is typically elevated more than three- to four- fold in ARDS.

Study objective

1) to determine whether blood transfusion leads to pulmonary leakage measured by PLI

2)to determine if pulmonary leakage is correlated with:
- the type of transfusion (erythrocytes, plasma or platelets)
- the amount of transfusion
- type of donor
- duration of storage of blood products
- the presence of HLA/HNA antibodies in donorblood
- the presence of bio-active lipid concentration in donorblood
- the presence of inflammation markers in the broncho alveolair fluid

Study design

In a prospective cohort study we will measure the pulmonary leakage index in 50 post operative cardiac surgery patients after multiple blood transfusions. Furthermore a mini lavage ot the lungs will be done. This is done as standard patient care on our ICU

PLI measurement will be done by labeling Transferrin in vivo, after i.v. injection of 67Gallium (Ga)-citrate, 4 MBq (physical half-life 78 h; Mallinckrodt Diagnostica, Petten, The Netherlands) as written before in studies from our research group. Demographic data from patients will be obtained out of the clinical files. Data about transfusions, donors and storage duration will be obtained via Sanquin. HLA/HNA analysis will be performed by Sanquin. Bio active lipids will be measured by thin plate chromatography.

Study burden and risks

none

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Cardiac surgery patients with post operative ICU admittance
Informed consent
>18 years
Recieving a minimum of 2 Fresh Frozen Plasma, 2 Packed Cells, 1 unit of platelets

Exclusion criteria

Immunosuppressive drugs

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2007
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL16131.018.07