Het effect van een bloedtransfusie bij kritiek zieke patiënten

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27009

Source
NTR

Brief title
TETRIS2

Health condition

EN: red blood cell transfusion, clearance, microcirculation, sepsis, intensive care medicine
NL: rode bloedcel transfusie, klaring, microcirculatie, sepsis, intensive care

Sponsors and support

Primary sponsor: Academic medical centre Amsterdam
Source(s) of monetary or material Support: fonds = verrichter = sponsor

Intervention

Outcome measures

Primary outcome

Phosphatidylserine exposure on donor RBCs

Secondary outcome

- Clearance of erythrocytes

- Expression of clearance markers other than PS

- Markers of immune cell and endothelial cell activation and adhesion

- Complete blood count

- Levels of fibrinogen, APTT, PTT and D-dimers in blood (to calculate DIC score)

- Markers of inflammatory host respons

- Sublingual microcirculatory density and perfusion velocity, as visualized with SDF

- Tissue oxygenation, as measured with NIRS

- Time on mechanical ventilation

- Duration of ICU stay

- Duration of hospital stay

- 28 day mortality

- DNA staining on residual red blood cell material,

- Red blood cell deformability, activation status and cell-binding ability

- Oxygen tension in the mitochondria (MitoPO2)

Study description

Background summary

Inclusion are going to take place in the Academic medical centre, Amsterdam, the Netherlands

Study design

Before transfusion and 1, 24 hours and 48 hours after transfusion

Intervention

Patients will receive biotinylated blood to be able to distinguish the donors blood from the

patients own blood

Contacts

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Eligibility criteria

Inclusion criteria

- Patients must receive an erythrocyte transfusion on the ICU, to correct for anemia

- Patients may not have received a transfusion with red blood cells, plasma or thrombocytes in the previous 24 hours

- Patients may not receive more than 1 unit of RBCs

- Patients may not be suspected of having an active bleeding

Exclusion criteria

- Patients who have not given informed consent

- Patients who pose difficulties in securing blood products (e.g. rare blood groups)

- Patients who receive more than 1 unit of RBCs in 1 transfusion episode

- No arterial catheter in situ

- Patients who received biotinylated blood before (earlier enrollment in TETRIS2)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2017
Enrollment:	86
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-07-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48722
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6419
NTR-old	NTR6596
CCMO	NL61833.018.17
OMON	NL-OMON48722

Study results