The Effects of Transfusion of Red blood cells In the critically ill II

Published: 21-07-2017
Last updated: 15-05-2024

To determine the effect of transfusion on the expression of PS in critically ill patients with and without inflammation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anaemias nonhaemolytic and marrow depression
Study type	Observational invasive

Summary

ID

NL-OMON48722

Source
ToetsingOnline

Brief title
TETRIS2

Condition

- Anaemias nonhaemolytic and marrow depression
- Ancillary infectious topics

Synonym
Anemia, blood deficiency

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Clearance, Erythrocyte transfusion, Sepsis, Storage time

Outcome measures

Primary outcome

Change in the expression of PS on erythrocytes before and after RBC transfusion

and the influence of an inflammatory state in the receiver.

Secondary outcome

* Clearance rate 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

* VO2 (oxygen uptake), DO2 (oxygen delivery), O2ER (oxygen extraction ratio)

* 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

Study description

Background summary

Blood transfusion in critically ill patients contributes to mortality, while the yield remains questioned. Mechanisms of adverse effects are unknown, but may include accelerated clearance from the circulation and vascular adherence shortly after transfusion, thereby impeding microcirculation, tissue oxygenation and heme-metabolism. Clearance of erythrocytes may be mediated by expression of *eat me* signals, such as phosphatidylserine (PS). Expression of PS *eat me* signals is enhanced during storage of erythrocytes in vitro. Also, sepsis was shown to increase PS eat me* signal expression, contributing to clearance in an ex vivo design. The finding that the presence of sepsis and increased storage time negatively influences the effect of erythrocyte transfusion at the tissue level, may alter transfusion or blood banking practice.

Study objective

To determine the effect of transfusion on the expression of PS in critically ill patients with and without inflammation.

Study design

A single center prospective cohort study

Study burden and risks

Detrimental effects of transfusion are thought to be more extensive in critically ill patients. Therefore, a study in this specific population is necessary. Patients who pose difficulties in securing blood products (rare blood groups) or who are difficult to match, will not be included. Prior to transfusion stored RBCs will be biotinylated (vitamine B8) to allow their indentification by flow cytometry. Preperation will be done under sterile conditions. Although in a healthy volunteer study 1 out of 8 subjects developed a transient positive test for antibody to biotinylated RBCs, at 11 months post transfusion antibodies to biotinylated RBCs has disappeared. Biotin labeling has no effect on RBC survival. Thus, biotinylation of RBCs is considered safe. Risk of participation related to analytic methods is considered to be very small, because assessments of the microcirculation and echocardiography are non-invasive and blood samples are drawn from an arterial catheter that is already in place as part of the standard patient care (there will be no burden from extra venapunctures).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients who will receive an erythrocyte transfusion in the ICU (to correct for anemia) and are not suspected of 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

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-08-2017
Enrollment:	86
Type:	Actual

Ethics review

Approved WMO

Date:	21-07-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	11-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	30-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	29-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	27-09-2019
Application type:	Amendment
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

ID: 27009
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61833.018.17
OMON	NL-OMON27009