# The Effects of Transfusion of Red blood cells In Sepsis

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To evaluate the effect of age of transfused erythrocytes on expression of *eat me* signals on erythrocytes in several critically ill patient populations (septic and non-septic patients) and to correlate these signals with parameters of impaired...

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| **Ethical review** | - |
| **Status** | Recruitment stopped |
| **Health condition type** | Ancillary infectious topics |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36804

**Source**
ToetsingOnline

**Brief title**
TETRIS, Transfusion in Sepsis

### Condition

- Ancillary infectious topics
- Decreased and nonspecific blood pressure disorders and shock

**Synonym**
Sepsis + blood poisoning

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** Erythrocyte transfusion, Microcirculation, Sepsis, Storage time

## Outcome measures

### Primary outcome

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

### Secondary outcome

- Expression of erythrocyte CD44, CD47, CD55, CD59, Band 3, MFG-E8, Gas6, IgG, levels of heme and complement in blood

- Expression of platelet CD62P, CD62E, CD63, and levels of microparticles sCD40L, sP-selectin, and thrombocyte-leukocyte complexes in blood and NBALF

- Levels of hemoglobin, erythrocytes, platelets, leucocytes and leucodifferentiation in blood

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

- Levels of ADAMTS13, active VWF and VWF multimer size in blood (experimental markers of DIC)

- Levels of TAT-complexes, pro-thrombin fragment F1+2,factor VIIa, tissue factor in blood (markers of coagulation)

- Levels of tissue type plasminogen activator inhibitor-1 (PAI-1) and plasmin-a2-antiplasmin complexes (PAP-complex) in blood (markers of fibrinolysis)

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

- Tissue oxygenation, as measured with NIRS

- Onset of TRALI

- Time on mechanical ventilation

- Duration of ICU stay

- Duration of hospital stay

- 28 day mortality

# Study description

### Background summary

Blood transfusion in critically ill patients contributes to mortality, while the yield remains questioned. Observational studies have shown a correlation between the age of transfused erythrocytes and adverse outcome. 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 evaluate the effect of age of transfused erythrocytes on expression of *eat me* signals on erythrocytes in several critically ill patient populations (septic and non-septic patients) and to correlate these signals with parameters of impaired microcirculation.

### Study design

A single centre randomized controlled trial

### Intervention

The transfusion of erythrocytes of < 8 days old, instead of the standard transfusion with erythrocytes that have been stored for 2-35 days.

### 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. Either patients receive erythrocytes according to standard care, or they receive solely fresh erythrocytes, which has a potential beneficial effect. Patients who pose difficulties in securing blood products (rare blood groups) or who are difficult to match, will not be included. Therefore, participation in this study has a potential benefit, while risk of participation related to the intervention is unaltered. 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). The additive burden of a non-directed bronchoalveolar mini-lavage is small because it is a frequently performed technique in mechanically ventilated patients in the ICU.

## 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 their first erythrocyte transfusion on the ICU to correct for anemia

## Exclusion criteria

- Patients who have not given informed consent
- Patients who pose difficulties in securing blood products (e.g. rare blood groups)
- Patients who are actively bleeding or are suspected for active bleeding (when a transfusion is given with the intention to treat bleeding according to the treating physician)
- Patients who receive more than 1 unit of red blood cells in the transfusion episode
- Patients who need a blood transfusion when there*s no fresh blood available

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Basic science |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 23-11-2011 |
| Enrollment: | 100 |
| Type: | Actual |

# Ethics review

Not available

# 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 | NL34692.018.11 |