# Highly restrictive vs normal red blood cell transfusion strategy in anemic critically ill patients - A feasibility trial

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Red blood cell disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON57318

**Source**
ToetsingOnline

**Brief title**
Very Restrictive Transfusion of Erythrocytes study

### Condition

- Red blood cell disorders

**Synonym**
Anemia

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Red Blood Cell, Restrictive, Transfusion

## Outcome measures

### Primary outcome

Primary outcome is feasibility measured by protocol compliance. Protocol compliance is defined as the percentage of red blood cell transfusion initiated below the assigned transfusion threshold.

### Secondary outcome

Secondary study parameters will include SOFA-score, number of protocol violations and incidence of protocol suspensions divided into any (suspected) major bleeding, necessary transfusion prior to (surgical) intervention and early signs of organ hypo perfusion. Early signs of hypo perfusion is divided into cardiac and elevated lactate levels of more than 4mmol/L (in conjunction with decreased SvO2) which cannot be attributed to other causes besides anemia. Other secondary study parameters include the presence of organ ischemia, use of life support, development of acute kidney injury stage 2 (KDIGO criteria), transfusion practices, 30-day mortality, duration of ICU and hospital stay, ICU re-admission rates and cost effectiveness.

# Study description

### Background summary

Red blood cell transfusion is considered a life-saving intervention. Over the past 20 years however, its potential for harm and even life-threatening complications have become apparent. Research in various patient groups has consistently shown that a restrictive transfusion policy, with a hemoglobin

(Hb) threshold of approximately 7.0 g/dL is safe or even associated with better outcomes. As a result, this has become the standard transfusion trigger. However, clinical observations indicate the potential for further lowering the transfusion threshold. This encourages us to investigate the possibility of adopting an even more restrictive transfusion threshold.

### Study objective

The primary objective is feasibility of a prospective randomized trial, to investigate whether a more restrictive RBC transfusion strategy of 5.0 g/dL (3.1 mmol/L) is non-inferior compared to the current transfusion threshold of 7.0 g/dL (4.3mmol/L).

### Study design

Prospective randomized controlled feasibility trial

### Intervention

Restrictive red blood cell (RBC) transfusion threshold: in case the Hb transfusion trigger of 5.0 g/dL is reached, 1 RBC unit at a time will be administered. The current transfusion threshold: in case the Hb transfusion trigger of 7.0 g/dL is reached, 1 RBC unit at a time will be administered.

### Study burden and risks

Anemia and red blood cell transfusions have been linked to higher morbidity and mortality rates in ICU patients. This patient population is already vulnerable with a high morbidity and mortality rate. Therefore, it is important to only transfuse when necessary.
This trial will assess the feasibility of reducing the transfusion threshold from 7.0 g/dL to 5.0g/dL. Participation in this trial will result in negligible burden. No additional blood samples are required, as routine blood sampling is hospital SOP and additional measurements can be included herein. Additional measurements include a daily ECG as well as urine output assessment, which are non-invasive. The intervention for this study will only occur during ICU admission. Given the high incidence of both transfusions and anemia in this patient population, there are no additional risks associated with either of these factors.

## Contacts

**Public**
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL
**Scientific**
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Inclusion criteria:
- patient is aged 18 years or older
- deferred informed consent
- hemoglobin concentration of 5.0 mmol/L (=8 g/dL) or lower

## Exclusion criteria

- Not expected to survive for 24 hours at time of assessment.
- Expected to stay in ICU for less than 48 hours.
- Inability to receive blood products or known to decline to blood transfusions (e.g., Je-hova*s Witnessess).
- Exclusion of specific subgroups:
Patients receiving extra-corporeal membrane oxygenation (VV or VA)
Patients with an acute coronary syndrome in the past 30 days
Patients following cardiac surgery
Patients admitted with both traumatic and non-traumatic brain injury (i.e. traumatic subarachnoid hemorrhage, cerebral infarction)

Patients with hemoglobinopathies such as sickle cell disease
Massive bleeding patients
Pregnant patients

# 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: | Prevention |

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-04-2025 |
| Enrollment: | 40 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Registration: | No |

# Ethics review

Approved WMO

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|---|---|
| Date: | 12-02-2025 |
| 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 | NL86532.018.24 |