

# Coagulation improvement after platelet transfusion in critically ill patients

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We propose an observational clinical trial in critically ill patients to investigate the effect and duration of platelet transfusion on coagulation, including platelet function and markers of endothelial activation in critically ill patients.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Platelet disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON44365

### Source

ToetsingOnline

### Brief title

Captain

### Condition

- Platelet disorders

### Synonym

low platelet count, Thrombocytopenia

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

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

## Intervention

**Keyword:** Coagulation, ICU, Platelet transfusion, Thrombocytopenia

## Outcome measures

### Primary outcome

The increase in platelet count and the effect on coagulation before and after platelet concentrate transfusion.

### Secondary outcome

Platelet increment at 2 and 4 hours

- Rotational thromboelastography (INTEM, EXTEM, FIBTEM)
- MCF, CT, CFT,  $\alpha$ -Angle.
- Classical coagulation tests
- PT, INR, aPTT
- Fibrinogen
- D-Dimer
- Multiplate
- AUC, slope.
- Trombin-antitrombin complexes
- Trombin generation
- Endothelial activation
- Syndecan
- Fragmentocytes

## Study description

## **Background summary**

Platelet transfusion is frequently administered to critically ill patients. However, there is a paucity of data about its effects on coagulation. Of note, opposite to the research hypothesis, recent investigations show that platelet transfusion is not favourable in patients with cerebral haemorrhage on antiplatelet therapy. To address the effects and duration of platelet transfusion on coagulation, we want to perform a thromboelastometric study in critically ill patients, scheduled for a single platelet transfusion.

## **Study objective**

We propose an observational clinical trial in critically ill patients to investigate the effect and duration of platelet transfusion on coagulation, including platelet function and markers of endothelial activation in critically ill patients.

## **Study design**

Single centre observational clinical trial.

## **Study burden and risks**

Critically ill patients differ from hematological patients in both causes of thrombocytopenia and the response to PLT transfusion. Detrimental effects of transfusion are thought to be more extensive in critically ill patients. Therefore, a study in this specific patient population is necessary.

## **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 need to be admitted to the Intensive Care Unit
- The indication for 1 unit of PLT concentrate, at physician\*s discretion.
- Arterial line to enable blood sampling.

### Exclusion criteria

- Contra-indication for PLT transfusion, e.g. TTP.
- The use of ticagrelor or clopidogrel.
- Severe active bleeding, e.g. bleeding that leads to multiple transfusions.
- No informed consent

## 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):	08-05-2018
Enrollment:	24
Type:	Actual

## Ethics review

Approved WMO	
Date:	28-11-2017
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	NL63679.018.17