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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Platelet disorders
Study type	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 tromboelastography (INTEM, EXTEM, FIBTEM)

• MCF, CT, CFT, α-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