The haemostatic effect of thawed deep-frozen platelets resuspended in thawed plasma versus room temperature stored platelets in platelet additive solution in the treatment of surgical bleeding; a randomized controlled non-inferiority trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57248

Source
ToetsingOnline

Brief title
MAFOD

Condition

- Other condition
- Vascular injuries

Synonym

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Massive haemorrhage

Health condition

Massaal bloedverlies ten gevolge van traumatisch letsel

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van Defensie;Stichting Ziektekosten Verzekering Krijgsmacht

Intervention

Keyword: Bloodplatelets, Hemorrhage, Transfusion, Trauma

Outcome measures

Primary outcome

Primary outcome is the percentage of patients achieved haemostasis at six hours (360 minutes) (as defined as the time in minutes from MTP activation to the moment a patient received no further blood product transfusions for two hours).

Secondary outcome

The secondary aims are

- Time to haemostasis (as defined as the time in minutes from MTP activation to the moment a patient received no further blood product transfusions for two hours)

- Total in-hospital blood component consumption (units)

- Fibrinogen administration (including blood component content)

- Laboratory parameters (e.g. platelet count, Haematocrit)

- Coagulation parameters (INR, fibrinogen levels, ROTEM® parameters).

- Mortality

- Hospital lenght of stay

- Intensive care lenght of stay

- Transfusion reactions

Study description

Background summary

Patients with surgical bleeding often require massive transfusion. The current standard advises to transfuse blood components in a balanced ratio (1:1:1 - erythrocytes:plasma:platelets) that equalizes whole blood transfusion. The Dutch-Ministry of Defence uses deep frozen platelets primarily due to logistical advantages. These deep-frozen platelets are associated with improved haemostasis and reduced in hospital blood product consumption in vitro and animal studies in comparison with liquid room stored (+22°C) buffy coat room temperature stored platelets. However, high quality evidence for usage of deep-frozen platelets in clinical trials is still scarce.

Study objective

the primary aim is to determine the effect of thawed deep-frozen platelets re-suspended in thawed deep-frozen plasma versus room temperature stored platelets in platelet additive solution for transfusion on the percentage of patients with surgical bleeding achieved haemostasis at six hours (360 minutes) (haemostasis is defined that a patient no further requires erythrocyte transfusion for two hours) The secondary aims are to determine the effect of thawed deep-frozen platelets re-suspended in thawed deep-frozen plasma versus room temperature stored platelets in platelet additive solution for transfusion in patients with surgical bleeding on (1) time to haemostasis (as defined as the time in minutes from MTP activation to the moment that a patient no further requires erythrocyte transfusion for two hours); (2) total in hospital transfused blood component consumption in different time intervals (up to 30-days or discharge); (3) fibrinogen administration in different time intervals (content of all blood products calculated measured according to previous research); (4) Laboratory parameters for blood gasses and electrolytes in different time intervals; (5) coagulation parameters in different time intervals; (6) mortality at 1, 3, 6, 12, 24 and 72 hours and 30-days; (7) hospital length of stay up to 30-days or discharge; (8) ICU stay up to 30-days or discharge; (9) occurrence of transfusion reactions.

Study design

Single blind randomized controlled non-inferiority trial

Intervention

transfusion with thawed deep-frozen platelets re-suspended in thawed deep-frozen plasma or transfusion with room temperature stored platelets in platelet additive solution in the first 48 hours after MTP activation.

Study burden and risks

The known burden and risks are not greater than the currently used blood platelets. The hypothesis is that patients who received deep-frozen platelets achieve hemostasis earlier. This is advantageous since, in addition to the possible survival advantage, less blood products are required which will result in a cost reduction.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients of 12 years or older*
2. Alive at hospital presentation
3. Order of massive transfusion package including platelet concentrate for surgical bleeding (e.g. traumatic bleeding or bleeding in transplantation surgery)
4. Signed deferred consent by patient, proxy, or parents, as applicable.

* it is imaginable that the exact age of a child at presentation on the emergency department is not known. At a confirmed age younger than 12, the patient will be excluded from analysis.

Exclusion criteria

- Refusal of blood product administration (e.g. confirmed prior to randomisation in the electronic patient file that patient is a Jehovah*s Witness)
- Known pregnancy
- Known to refuse resuscitation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2022
Enrollment:	158
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-07-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL75412.078.21