Transfusion of plasma to prevent bleeding in ICU patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27877

Source
NTR

Brief title
TOPIC trial

Health condition

Fresh frozen plasma
Coagulopathy
Intensive Care
Adverse effects

Dutch:
Plasma
Stollingsstoornissen
Intensive Care
Bijwerkingen

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam, The Netherlands
Source(s) of monetary or material Support: ZonMw
Postbus 93 245
2509 AE Den Haag
info@zonmw.nl

project number: 80-82310-97-10069

Intervention

Outcome measures

Primary outcome

The primary outcome of this study will be a procedure related relevant bleeding, occurring within 24 hours after the procedure.

Secondary outcome

1. Minor bleeding within 24 hours of the intervention;

2. Onset of acute lung injury within 48 hours;

3. Correction of INR to <1,5 (after the transfusion of FFP and before the procedure, only in the transfusion arm);

4. Correction of coagulation variables;

5. Length of ventilation days;

6. Length of ICU stay;

7. ICU mortality;

8. Serious adverse events.

Study description

Background summary

Rationale:

Fresh frozen plasma (FFP) is an effective therapy to correct for a deficiency of multiple coagulation factors during bleeding. In past years, use of FFP has increased, in particular in patients on the Intensive Care Unit (ICU), and has expanded to include prophylactic use in patients with a coagulopathy prior to undergoing an invasive procedure. Retrospective studies suggest that prophylactic use of FFP does not prevent bleeding, but carries the risk of transfusion-related morbidity. However, up to 50% of FFP is administered to non-bleeding ICU patients.

Objective:

With the aim to restrict inappropriate FFP transfusions to critically ill patients, a randomized clinical trial will be conducted in a subgroup of ICU patients with a coagulopathy undergoing an invasive procedure. The objective is to assess the effectiveness and costs of prophylactic FFP transfusion (current practice) compared to no prophylactic transfusion, in non-bleeding ICU patients with a coagulopathy, prior to undergoing an invasive procedure.

Study design:

Prospective, multicentre, randomized, open-label, blinded end point evaluation (PROBE) design.

Study population:

ICU patients of 18 years and older with prolonged INR, who are undergoing an invasive procedure (insertion of a central venous catheter, chest drain, percutaneous tracheostomy, or percutaneous drainage of abscess/fluid collection).

Intervention:

Omitting prophylactic transfusion of FFP prior to an invasive procedure compared to transfusion of a fixed dose of 12 ml/kg.

Main study parameters/endpoints:
Primary outcome measure is relevant bleeding. Secondary outcome measures are minor bleeding, correction of INR, onset of acute lung injury, length of ventilation days, length of ICU stay and costs.

Study objective

Fresh frozen plasma (FFP) is an effective therapy to correct a deficiency of multiple coagulation factors during bleeding. In past years, use of FFP has increased, in particular in patients on the intensive care unit (ICU), and has expanded to include prophylactic use in patients with a coagulopathy prior to undergoing an invasive procedure. Retrospective studies suggest that prophylactic use of FFP does not prevent bleeding., but carries the risk of transfusion-related morbidity. However, up to 50% of FFP is administered to non-bleeding ICU patients.
With the aim to restrict inappropriate FFP transfusions to critically ill patients, a randomized clinical trial will be conducted in a subgroup of ICU patients with a coagulapathy undergoing

an invasive procedure. The objective is to assess the effectiveness and costs of prophylactic FFP transfusion (current practice) compared to no prophylactic transfusion in these patients.

Study design

1. Identify eligible patients;

2. Randomisation after informed consent is signed;

3. Draw of baseline blood values (including coagulation parameters);

4. Transfusion of FFP or no transfusion of FFP;

5. Second draw of blood in case the subject was randomised for FFP transfusion;

6. Planned intervention/procedure (placement central venous catheter, tracheotomy, chest tube of abscess drainage);

7. 1 hour after procedure: assessment of bleeding severity;

8. 24 hours after procedure: assessment of bleeding severtity and chest x-ray (to determine lung injury).

Intervention

Omitting prophylactic transfusion of FFP prior to an invasive procedure compared to transfusion of a fixed dose of 12 ml/kg.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients admitted to the ICU of 18 years and older;

2. INR >1,5 and <3,0;

3. Undergoing an invasive procedure, including insertion of a central venous catheter, a chest drain, percutaneous tracheotomy or drainage of abscess or fluid collection.

Exclusion criteria

1. Clinically overt bleeding at the time of the procedure;

2. Thrombocytopenia <30*109/L;

3. Use of abciximab, tirofiban, ticlopidine or activated protein C;

4. Use of acenocoumarol, fenprocoumon or warfarin;

5. Use of prothrombin complex concentrate prior to procedure;

6. Use of heparin <1 hour before the procedure;

7. Use of therapeutic doses of low molecular weight heparin <12 hours before the procedure;

8. History of congenital or acquired coagulation factor deficiency or bleeding diathesis;

9. No informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2010
Enrollment:	400
Type:	Actual

Ethics review

Positive opinion

Date:	26-03-2010
Application type:	First submission

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
NTR-new	NL2138
NTR-old	NTR2262
Other	MEC AMC / ZonMw : 10/035 / 80-82310-97-10069 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A