Onderzoek naar de noodzaak van correctie van bloedplaatjestekort voor het plaatsen van een centraal veneuze lijn

No registrations found.

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

Summary

ID

NL-OMON27018

Source
NTR

Brief title
PACER

Health condition

Central venous catheter, CVC, centraal veneuze lijn, coagulopathy, coagulopathie, platelet count, thrombocytopenia, trombocytopenie

Sponsors and support

Primary sponsor: Acamedic Medical Center
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

A procedure-related relevant bleeding, occurring within 24 hours after the procedure. A WHO grade 2-4 (appendix I) up to 24 hours of randomization is defined as relevant bleeding.
Secondary study parameters/endpoints (if applicable)

Secondary outcome

- WHO grade 1 bleeding within 24 hours of CVC placement (appendix I)

- Adjusted WHO bleeding score, HEME-bleeding score (appendices II and III)

- Allergic transfusion reaction within 24 hours

- Onset of acute lung injury within 48 hours.

- Length of hospital stay

- Number of RBCs and PC transfusions within 24 hours

- Costs

Hemoglobin and platelet count will be measured prior to the procedure and one hour and at 24 hours after the procedure and when clinically indicated. This is according to standard care.

Study description

Background summary

Critically ill and hematologic patients undergoing therapy need a central venous catheter (CVC). These patients often suffer from thrombocytopenia at the moment of CVC placement. The current national and international guidelines support correction of thrombocytopenia up to a platelet count of 50 x 109/L prior CVC placement. There is, however, no evidence to support correction of thrombocytopenia. On the other hand it has been proven that transfusion of platelets concentrates (PC) can be complicated by serious side effects. Furthermore, transfusion of PC is expensive. Retrospective studies suggest it is safe to place CVC independent of the platelet count down to 10 x 109/L. Our objective is to determine whether not correcting thrombocytopenia prior to CVC placement is non-inferior compared to correcting thrombocytopenia, in a controlled setting.

Study objective

Not correcting thrombocytopenia prior to CVC placement in patients is non-inferior compared to correcting thrombocytopenia.

Study design

Directly after CVC insertion, 1 hour, 24 hours.

Intervention

Eligible patients will be randomly assigned to either receiving one unit of platelet concentrate, or no platelet concentrate. There will be no placebo treatment. Rescue platelet concentrate will be available for administration at clinicians' discretion. Blinding for the outcome will be performed for the researcher, not for the physicians and patients.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age>18 years

2. Need for CVC placement at the clinician's discretion

3. Platelet count between 10–50x109/L

4. INR<3.0

5. Informed consent

Exclusion criteria

1. Use of therapeutic anticoagulant therapy, except single antiplatelet therapy

2. Contra-indication for PC transfusion, such as Thrombotic thrombocytopenic purpura, or Congenital IgA deficiency

3. Randomization in the previous 24 hours

4. Patients with a history of congenital or acquired coagulation factor deficiency or bleeding diathesis

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2016
Enrollment:	392
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-01-2016
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	NL5534
NTR-old	NTR5653
Other	843002625, ZonMW : 2015_278, METC AMC

Study results

Summary results
None