Correction of Sub-clinical Prolongation of COAGulation Tests and/or Low Platelets before TRACHeotomy. (Randomized controlled trial).

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21788

Source
Nationaal Trial Register

Brief title
The COAG-TRACH study.

Health condition

ICU-patients with sub-clinical lengthening of coagulation tests (PTT 14.7 – 20 seconds, platelets < 100 x 109/L) or the use of Ascal® planned for percutaneous tracheotomy

Sponsors and support

Primary sponsor: Academic Medical Center,
Departement of Intensive Care
Amsterdam, The Netherlands

Intervention

Outcome measures

Primary outcome

The volume of blood loss during PDT.
The intensity of intra-tracheal bleeding.
Time until no blood is visible in tracheal aspirates.

Secondary outcome

The amount of bloodproducts used during and after tracheotomy.

Study description

Background summary

Background of the study:

Percutaneous dilational tracheotomy (PDT) is increasingly performed in mechanically ventilated intensive care unit (ICU)–patients. One of the complications of PDT, however, is peri-procedural bleeding, although the risk is normally very low. A large majority of ICU–patients demonstrate abnormalities in the coagulation system, varying from sub-clinical prolongation of coagulation tests and/or low platelets, to more severe coagulation disorders, better known as disseminated intravascular coagulation (DIC). For prolongation of coagulation tests (PTT > 20 seconds) and low platelets (platelets < 50 x 10e9/L), usually plasma and platelet concentrates are transfused before tracheotomy is performed. There are no clear guidelines on prolongation of PTT > 14.7 seconds, platelets < 100 x 10e9/L and patients using Ascal. Transfusion of blood products bears the risk of transmission of infectious diseases. In addition, the use of plasma products increases the risk of transfusion-associated acute lung injury (TRALI). Furthermore, it is uncertain whether plasma and/or platelets transfusion truly influences the risk of bleeding in patients with sub-clinical prolongation of coagulation tests and low platelets during PDT

Objective of the study:

To determine if patients with sub-clinical lengthening of coagulation test, low platelets or use of Ascal have increased risk of clinical significant bleeding during and after tracheotomy.

Study design:

Randomized controlled trial

Study population:

ICU-patients, older than 18 years, with sub-clinical lengthening of coagulation tests (PTT 14.7 – 20 seconds, platelets < 100 x 10e9/L) or the use of Ascal who recieve a tracheotomy

Intervention:

In group 1 patients receive platelets and/or plasma before PDT until normal values are reached. In group 2 patients do not receive platelets and/or plasma.

Primary study parameters/outcome of the study:

the volume of blood loss during PDT
the intensity of intra-tracheal bleeding
time until no blood is visible in tracheal aspirates

Secundary study parameters/outcome of the study (if applicable):

The amount of bloodproducts used during and after tracheotomy

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):

All interventions are part of the standard care surrounding patients that recieve tracheotomy. Therefore the extent of the burden should be regarded as small.
Bloodproducts will be available for immediate administration during PDT, if necessary to decrease the risk of bleeding.

Study objective

Correction of sub-clinical prolongation of coagulation tests (i.e., PTT between 14.7 – 20 seconds and platelets < 100 x 109/L) and transfusion of platelets in patients with Ascal®, significantly decreases the incidence of clinical significant peri-procedural bleeding.

Intervention

In group 1 patients receive platelets and/or plasma before PDT until normal values are reached. In group 2 patients do not receive platelets and/or plasma.

Contacts

Public
Academic Medical Center,
Departement of Intensive Care,
Meibergdreef 5,
D.P Veelo
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666345
Scientific
Academic Medical Center,
Departement of Intensive Care,

Meibergdreef 5,
D.P Veelo
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666345

Eligibility criteria

Inclusion criteria

1. Sub-clinical lengthening of coagulation;
2. Tests and or low platelets;
3. Use of Ascal;
4. Planned PDT;
5. Age > 18 years;
6. Informed consent.

Exclusion criteria

1. Contraindication for PDT (i.e., surgical tracheotomy is preferred);
2. Contra-indications for transfusion of blood products;
3. Contra-indication for correction of coagulation disorders;
4. PTT > 20 seconds;
5. Use of clopidogrel.

Study design

Design

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

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-07-2006
Enrollment:	152
Type:	Anticipated

Ethics review

Positive opinion Date:	29-05-2006
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	NL634
NTR-old	NTR694
Other	: N/A
ISRCTN	ISRCTN31808827

Study results

Summary results

1) Kollef MH, Ahrens TS, Shannon W. Clinical predictors and outcomes for patients requiring tracheostomy in the intensive care unit. Crit Care Med 1999:27:1714-1720.;
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employed in the intensive care unit? An international utilization review. Am J Respir Crit Care Med 2000:161:1450-1458.;
3) Fischler L, Erhart S, Kleger GR, Frutiger A. Prevalence of tracheostomy in ICU patients. A nation-wide survey in Switzerland. Intensive Care Med 2000:26:1428-1433;
4) Frutos-Vivar F, Esteban A, Apezteguia C, Anzueto A, Nightingale P, Gonzalez M, Soto L, Rodrigo C, Raad J, David CM, Matamis D, G DE. Outcome of mechanically ventilated patients who require a tracheostomy. Crit Care Med 2005:33:290-298.;
5) Rodriguez JL, Steinberg SM, Luchetti FA, Gibbons KJ, Taheri PA, Flint LM. Early tracheostomy for primary airway management in the surgical critical care setting. Surgery 1990:108:655-659;
6) Heffner JE. Medical indications for tracheotomy. Chest 1989:96:186-190;
7) Marsh HM, Gillespie DJ, Baumgartner AE. Timing of tracheostomy in the critically ill patient. Chest 1989:96:190-193;
8) Heffner JE, Miller KS, Sahn SA. Tracheostomy in the intensive care unit. Part 1: Indications, technique, management. Chest 1986:90:269-274;
9) Heffner JE, Miller KS, Sahn SA. Tracheostomy in the intensive care unit. Part 2: Complications. Chest 1986:90:430-436;
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13) Gajic O, Moore SB. Transfusion-related acute lung injury. Mayo Clin Proc 2005:80:766-770.