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

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21788

Bron
NTR

Verkorte titel
The COAG-TRACH study.

Aandoening

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

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2006
Aantal proefpersonen:	152
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-05-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL634
NTR-old	NTR694
Ander register	: N/A
ISRCTN	ISRCTN31808827

Resultaten

Samenvatting resultaten

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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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;
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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;
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13) Gajic O, Moore SB. Transfusion-related acute lung injury. Mayo Clin Proc 2005:80:766-770.