

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21788

### Source

NTR

### 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 10<sup>9</sup>/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 10<sup>9</sup>/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 10<sup>9</sup>/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 10<sup>9</sup>/L) or the use of Ascal who receive 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

Secondary 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 receive 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  $< 100 \times 10^9/L$ ) 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**

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