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

Published: 12-07-2006
Last updated: 20-05-2024

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.

Ethical review	Approved WMO
Status	Pending
Health condition type	Procedural related injuries and complications NEC
Study type	Interventional

Summary

ID

NL-OMON29953

Source
ToetsingOnline

Brief title
The COAG-TRACH study

Condition

- Procedural related injuries and complications NEC

Synonym
clinical significant blood loss, complications

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: blood loss, coagulation, platelets, tracheotomy

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

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

Study objective

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

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.

Study burden and risks

The trial can only be done in ICU-patients. Due to the nature of their illness and the frequent use of sedatives many patients are incapacitated.
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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

sub-clinical lengthening of coagulation tests and or low platelets
use of Ascal
planned PDT
age > 18 years
Informed consent

Exclusion criteria

contraindication for PDT (i.e., surgical tracheotomy is preferred)
contra-indications for transfusion of blood products
contra-indication for correction of coagulation disorders
PTT > 20 seconds
use of clopidogrel

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2006
Enrollment:	152

Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL12894.018.06
Other	pending