

Correction of sub-clinical prolongation of COAGulation tests and/or low platelets before TRACHeotomy: randomised controlled trial

Submission date 19/07/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/07/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/08/2012	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR694

Study information

Scientific Title

Acronym

The COAG-TRACH study

Study objectives

Correction of sub-clinical prolongation of coagulation tests (i.e. partial thromboplastin time [PTT] between 14.7 - 20 seconds and platelets less than $100 \times 10^9/l$) and transfusion of platelets in patients taking Ascal®, significantly decreases the incidence of clinically significant peri-procedural bleeding.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Randomised, single blinded, active controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Blood coagulation disorders, percutaneous tracheotomy (PDT)

Interventions

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.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

The amount of blood products used during and after tracheotomy

Completion date

01/07/2009

Eligibility

Key inclusion criteria

1. Sub-clinical lengthening of coagulation
2. Tests and/or low platelets
3. Use of Ascal®
4. Planned percutaneous tracheotomy (PDT)
5. Aged greater than 18 years
6. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Contraindications for percutaneous tracheotomy (PDT) (i.e. surgical tracheotomy is preferred)
2. Contraindications for transfusion of blood products
3. Contraindication for correction of coagulation disorders
4. PTT greater than 20 seconds
5. Use of clopidogrel

Date of first enrolment

01/07/2006

Date of final enrolment

01/07/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Centre (AMC) (The Netherlands) - Department of Intensive Care

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The Netherlands) - Department of Intensive Care

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2012		Yes	No