ISRCTN31808827 https://doi.org/10.1186/ISRCTN31808827

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/07/2006	**Overall study status** Completed	
Last Edited 02/08/2012	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 x 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

Study design
Randomised, single blinded, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
The amount of blood products used during and after tracheotomy

Overall study start date
01/07/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
152

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

Sponsor details
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
University/education

Website
http://www.amc.uva.nl

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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