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Feasibility and safety of inhaled heparin in intubated and mechanically ventilated patients: a randomised controlled trial comparing three doses of inhaled unfractionated heparin

Submission date
22/01/2007

Recruitment status
No longer recruiting

Registration date
22/01/2007

Overall study status
Completed

Last Edited
22/01/2007

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
N/A

Study information

Scientific Title

Acronym
NebHep study

Study objectives
We hypothesise that unfractionated heparin could be of benefit in treatment of Acute Lung Injury (ALI). Delivering heparin directly to the pulmonary compartment may attenuate fibrin depositions more effectively while reducing the risk of bleeding as a result of systemic anticoagulant effects. Intubated and mechanically ventilated patients may also benefit from such strategies since mechanical ventilation may cause injury very similar to ALI and pneumonia.

Before future investigations of therapeutic effects of nebulised unfractionated heparin in mechanically ventilated patients with ALI can be performed, this therapeutic strategy needs to be tested on its feasibility and safety. Therefore, in this study we will evaluate the feasibility and safety of treatment with inhaled heparin in intubated and mechanically ventilated patients without ALI. We consider treatment with inhaled heparin to be safe if none of the included patients show a more than 25% increase of area under the curve of serial anti-Xa measurements in plasma.
If treatment with inhaled heparin is safe, we will perform a new study in patients with ALI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised, placebo 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
Mechanical ventilation

Interventions
Administration of unfractionated heparin or placebo by aerosol generator (AeronebPro, Aerogen Inc., Sunnyvale, CA, USA) during mechanical ventilation.

Blood samples and lung fluid will be collected before treatment and at one, three, six and 24 hours after the beginning of the last nebulisation.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Unfractionated heparin

Primary outcome measure
Area under the curve of serial anti-Xa measurements in plasma.

Secondary outcome measures
1. Blood:
a. Area under the cure of serial aPTT measurements
b. Whole blood clotting time lung fluid:
area under the curve of serial anti-Xa measurements, heparin, factor VII/VIIa, Tissue Factor (TF), Tissue Factor Pathway Inhibitor (TFPI)-antigen, TFPI activity, protein C/activated protein C, prothrombin fragment 1.2, Thrombin-AntiThrombin III complex (TATc), Endogenous Thrombin Potential (ETP), Fibrin monomers, soluble thrombomodulin, Plasmin-AntiPlasmin complexes (PAPc), Plasminogen Activator Inhibitor (PAI)
2. Occurrence and severity of bleeding events

Overall study start date
01/02/2007

Completion date
01/02/2008

Eligibility

Key inclusion criteria
1. Patients who are mechanically ventilated
2. Aged more than 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
24

Key exclusion criteria
1. Acute Lung Injury (consensus criteria)
2. Increased risk of bleeding:
a. Within 24 hours after major surgery
b. Thrombocytes less than 50 x 10^9/L
c. Prothrombin Time (PT) more than 20 seconds
d. Activated Partial Thromboplastin Time (APTT) more than 60 secconds
3. Acute bleeding at any site
4. Pregnancy or breast feeding

Date of first enrolment
01/02/2007

Date of final enrolment
01/02/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

Sponsor details

P.O. Box 22660
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Center (AMC) (The Netherlands)

Alternative Name(s)
Academic Medical Center, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

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