

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	☒ Prospectively registered ☐ Protocol
Registration date 22/01/2007	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 22/01/2007	Condition category Respiratory	☐ 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

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

Primary study design

Interventional

Study design

Randomised, placebo controlled, parallel group trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

1. Blood:

a. Area under the curve of serial aPTT measurements

b. Whole blood clotting time lung fluid:

area under the curve of serial anti-Xa measurements, heparin, factor VII/VIII, 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

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 $50 \times 10^9/L$

c. Prothrombin Time (PT) more than 20 seconds

d. Activated Partial Thromboplastin Time (APTT) more than 60 seconds

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)

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, Centre Médical Académique, ACADEMISCH MEDISCH CENTRUM AMSTERDAM, Academic Medical Center (Amsterdam), AMC

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration