Feasibility and Safety of Inhaled Heparin in Intubated and Mechanically Ventilated Patients: A Randomized Controlled Trial Comparing Three Doses of Inhaled Unfractionated Heparin.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27158

Source NTR

Brief title NebHep study

Health condition

Mechanically ventilated patients without ALI

Sponsors and support

Primary sponsor: Academic Medical Centre, Amsterdam **Source(s) of monetary or material Support:** -

Intervention

Outcome measures

Primary outcome

1 - Feasibility and Safety of Inhaled Heparin in Intubated and Mechanically Ventilat ... 7-05-2025

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

Secondary outcome

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, TF, TFPIantigen, TFPI activity, protein C / activated protein C, prothrombine fragment 1.2, TATc, ETP (Endogenous Thrombin Potential), Fibrin monomers, soluble thrombomodulin, PAPc, PAI; 2. Occurrence and severity of bleeding events.

Study description

Background summary

Alveolar fibrin deposition is a hallmark of acute lung injury (ALI), Pulmonary coagulopathy is, the result of activation of coagulation and inhibition of fibrinolysis.

We hypothesize that unfractionated heparin could be of benefit in treatment of ALI. 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 nebulized 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. If safe, we will perform a new study in patients with ALI.

Study objective

We hypothesize that unfractionated heparin could be of benefit in treatment of 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 nebulized 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 non of the included patients show a >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.

Intervention

Administration of unfractionated heparin or placebo by aerosol generator (AeronebPro, Aerogen Inc., Sunnyvale, CA, USA) during mechanical ventilation. Bloodsamples and lungfluid will be collected before treatment and at 1, 3, 6 and 24 hours after the beginning of the last nebulization

Contacts

Public Academic Medical Center (AMC) IC Unit. P.O. Box 22660 I.I. Hofstra Meibergdreef 9 IC Unit, C3-423 Amsterdam 1100 DD The Netherlands +31(0)205668224Scientific Academic Medical Center (AMC) IC Unit, P.O. Box 22660 J.J. Hofstra Meibergdreef 9 IC Unit, C3-423 Amsterdam 1100 DD The Netherlands +31(0)205668224

Eligibility criteria

Inclusion criteria

- 1. Patients who are mechanically ventilated;
- 2. Age > 18 years.

Exclusion criteria

- 1. Acute Lung Injury (consensus criteria);
 - 3 Feasibility and Safety of Inhaled Heparin in Intubated and Mechanically Ventilat ... 7-05-2025

- 2. Increased risk of bleeding:
- a. Within 24 hours after major surgery;
- b. Thrombocytes < 50 * 109 / L;
- c. PT > 20 sec;
- d. APTT > 60 sec;
- 3. Acute bleeding at any site;
- 4. Pregnancy or breast feeding.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2007
Enrollment:	24
Туре:	Anticipated

Ethics review

Not applicable Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

4 - Feasibility and Safety of Inhaled Heparin in Intubated and Mechanically Ventilat ... 7-05-2025

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

ID
NL836
NTR849
: N/A
ISRCTN28587216

Study results

Summary results

N/A