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

Gepubliceerd: 07-12-2006 Laatst bijgewerkt: 18-08-2022

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...

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON27158

**Bron**
NTR

**Verkorte titel**
NebHep study

**Aandoening**

Mechanically ventilated patients without ALI

### Ondersteuning

**Primaire sponsor:** Academic Medical Centre, Amsterdam
**Overige ondersteuning:** -

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### Onderzoeksproduct en/of interventie

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

# Contactpersonen

## Publiek

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)20 5668224

## Wetenschappelijk

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)20 5668224

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Acute Lung Injury (consensus criteria);
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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Blindering: | Open / niet geblindeerd |
| Controle: | Placebo |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-02-2007 |
| Aantal proefpersonen: | 24 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL836 |
| NTR-old | NTR849 |
| Ander register | : N/A |
| ISRCTN | ISRCTN28587216 |

# Resultaten

**Samenvatting resultaten**
N/A