The HEPALI Study

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Nebulization of heparin will have a beneficial effect on pulmonary coagulopathy, reflected in reduction of pulmonary coagulation activation in the broncho-alveolar lavage fluid, and will decrease pulmonary vascular permeability reflected in a...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28056

Bron
NTR

Verkorte titel
HEPALI

Aandoening

1. Acute Lung Injury;

2. Acute Respiratory Distress Syndrome.

Ondersteuning

Overige ondersteuning: Self funding research.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. TATc in BAL fluid;
2. PLI.

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction

Acute lung injury (ALI) and acute respiratory distress syndrome (ARDS) are potentially lethal conditions, responsible for a considerable amount of admissions to the Intensive Care Unit (ICU) and for which, at present, only supportive care is available.

Pulmonary edema, as a result of increased pulmonary vascular permeability caused by proinflammatory changes, together with pulmonary coagulopathy, resulting in alveolar fibrin deposition and disturbed fibrin turnover, are the hallmarks of ALI/ARDS. The alveolar fibrin deposition is in part comparable to the intravascular deposition of fibrin in patients with sepsis and disseminated intravascular coagulation and may be aggravated by mechanical ventilation.

Based on a substantial body of evidence, both in vitro and in vivo, there is rationale to intervene in the pulmonary coagulopathy with anticoagulants in general, and with heparin in particular, in order to attenuate lung injury. Delivering heparin directly into the pulmonary compartment may attenuate fibrin depositions more effectively than systemic administration of heparin, while reducing the risk of bleeding as a result of systemic anticoagulant effects. In sheep, nebulization of heparin has been found to be beneficial. Furthermore, the nebulization of heparin to the lower respiratory tract is feasible and safe. In pediatric patients with inhalation injuries, heparin nebulization significantly reduced mortality.

With a bedside radionuclide method the pulmonary leak index (PLI) can be obtained as a measure of vascular leakage. The PLI is an ideal instrument to measure effects of therapy on pulmonary vascular leakage, since serial measurements can be performed.
Hence, nebulization of heparin may have a beneficial effect on pulmonary coagulopathy and may subsequently decrease pulmonary vascular permeability.

Study design

In a prospective, open-label, placebo controlled, randomised clinical trial we will evaluate the effects of heparin nebulization in mechanically ventilated patients with ALI/ARDS.

Objectives

1. To determine whether nebulization of heparin decreases coagulation activation in the pulmonary compartment (i.e. BAL fluid);

2. to determine whether nebulization of heparin decreases pulmonary vascular permeability.

Doel van het onderzoek

Nebulization of heparin will have a beneficial effect on pulmonary coagulopathy, reflected in reduction of pulmonary coagulation activation in the broncho-alveolar lavage fluid, and will decrease pulmonary vascular permeability reflected in a reduction of the PLI.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Nebulization of heparin (100,000 IU) or placebo every 8 hrs during 24 hrs. Before the first and after the last nebulization bronchoscopy will be performed to obtain bronchoalveolar lavage fluid of both the affected and the non-affected lung. At the same time measurement of the PLI will be performed.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria
All patients being intubated and mechanically ventilated in the ICU, who meet the

International Consensus Criteria of ALI or ARDS:

1. Informed consent;

2. Age: 18-80 years;

3. Recent onset of ALI or ARDS (i.e. <48 hrs).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Acute bleeding at any site;

2. Increased risk of bleeding:

Thrombocytes < 50 x 109/L

aPTT > 60 sec

PT > 20 sec, or INR > 1.7;

3. Within 24 hours after major surgery;

4. Proven or clinically suspected heparin induced thrombocytopenia;

5. Hemorrhagic diathesis;

6. Heparin allergy;

7. Pregnancy or breast feeding.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	28
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	NL1076
NTR-old	NTR1109
Ander register	VU medical center : N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A