Respiratory, hemodynamic and inflammatory effects of induced HypothermiA using NoVAtherm with extra corporeal membrane ventilator iLA-Activve in patients ARDS

Gepubliceerd: 29-11-2013 Laatst bijgewerkt: 19-03-2025

Induced hypothermia to 32-34 degree Celsius using NovathermTM with extracorporeal iLA-Activve MinilungTM allows for a reduction in minute volume ventilation needed for adequate gas exchange in patients with ARDS, with a concomitant decrease in work...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26548

Bron
Nationaal Trial Register

Verkorte titel
HAVAnA trial

Aandoening

Acute respiratory distress syndrome

Ondersteuning

Primaire sponsor: Department of Intensive Care, Academic Medical Centre, University of Amsterdam
Overige ondersteuning: Department of Intensive Care, Academic Medical Centre, University of Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Minute volume ventilation

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In ARDS, it is often not possible to adhere to protective ventilation strategies using low tidal volumes and low peak inspiratory pressures. Induced hypothermia to 32-34□C allows for a reduction in minute volume ventilation. By using NovathermTM, cooling of patients can be combined with extracorporeal carbon dioxide removal via the iLA-Activve MinilungTM..

Objective: Does induced hypothermia using NovathermTM in combination with iLA-Activve MinilungTM result in a reduction in minute volume ventilation and work of breathing in patients with ARDS?

Study design: Randomized controlled open label trial

Study population: Mechanically ventilated patients with ARDS admitted to the Intensive Care Unit.

Intervention (if applicable): CO2 removal using iLA-Activve MinilungTM, with or without induced hypothermia to 32-34 ºC, during 12 hours.

Main study parameters/endpoints: Minute Volume Ventilation

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: To connect the iLA-Activve MinilungTM device, a double lumen cannula of 18 French Gauge will be inserted in the jugular or femoral vein under ultrasound guidance. Participants will donate a total 30 ml of blood and will undergo non-invasive measurements, such as calorimetry and echocardiography. Since this patient population with severe acute respiratory distress syndrome will need mechanical ventilation, this study can only be executed at an intensive care unit, with sedated patients. There are clear possible benefits in participation, as the treatment under investigation may improve hemodynamic, respiratory and inflammatory parameters. There is a risk of adverse events, including bleeding or thrombosis.

Doel van het onderzoek

Induced hypothermia to 32-34 degree Celsius using NovathermTM with extracorporeal iLA-Activve MinilungTM allows for a reduction in minute volume ventilation needed for adequate gas exchange in patients with ARDS, with a concomitant decrease in work of breathing and increase in pulmonary compliance, resulting in less lung injury and less time on the ventilator.

We furthermore hypothesize that reducing minute volume ventilation by reducing positive peak inspiratory pressure levels using NovathermTM combined with the iLA-Activve MinilungTM will result in an increase in cardiac output and right ventricular function.

Onderzoeksopzet

Before connection to the iLA-Activve MinilungTM, at 2 hours and 24 hours after the initiation of treatment, a two dimensional transthoracic echocardiography (TTE) will be carried out. Cardiac output will be estimated with a combined two dimensional (2D) and Doppler approach, which allows calculation of the stroke volume. Also, E/A ratio will be estimated as well as pulmonary pressures.
At the same time points, energy expenditure will be measured using indirect calorimetry.
After completion of the study protocol, a non-directed mini broncho-alveolar lavage (miniBAL) will be performed by instilling 20 cc of normal saline in the lung via the endotracheal tube, after which fluid will be retrieved.

At start of treatment and after 24 hours of start of treatment, blood will be drawn form an intra-arterial catheter which is already in place as part of ICU standard care. In total a maximum of two times 15 ml of blood will be drawn.
Patients receiving hypothermia are sedated and passively rewarmed at 1 degree Celsius per hour, after the period of hypothermia. Control patients and patients, using the MinilungTM while maintaining normotemperature during at least 12 hours; receive no additional sedation, if not required according to the treating physician.
In control patients receiving standard care, echocardiography, calorimetry, miniBAL and blood drawn will be performed at same time points, after randomization.

Onderzoeksproduct en/of interventie

CO2 removal using iLA-Activve MinilungTM, with or without induced hypothermia to 32-34 ºC, during 12 hours.

Contactpersonen

Publiek

Meibergdreef 9
N.P. Juffermans
Amsterdam 1105 AZ

The Netherlands
+31 (0)20 5662509

Wetenschappelijk

Meibergdreef 9
N.P. Juffermans
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5662509

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria

- Suffering of a clinical condition associated with ARDS

- ARDS according to the Berlin definition [11] (P/F < 200 with PEEP > 5 cmH2O; bilateral pulmonary opacities at chest X-ray; respiratory failure not fully explained by cardiac failure or volume overload)

- Mechanical ventilation with maximum inspiratory pressure levels (Pmax) of > 30 cm H2O, while maintaining tidal volume ventilation of 6-8 ml/kg ideal body weight and permissive hypercapnia with an arterial pH < 7.35.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

4.3 Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Contra-indication for (low dose of) heparin

- Severe shock, requiring norepinephrin dose of > 25 µg/kg/hour

- Severe hypoxia, requiring referral for extra corporeal membrane oxygenation

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	04-07-2013
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-11-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39735
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4148
NTR-old	NTR4349
CCMO	NL42038.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39735

Resultaten

Samenvatting resultaten
N/A