Does reducing pulmonary hyperciculation affect pulmonary capillary permeability in severe ARDS patients? - a pilot study.

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To study the effect of reducing the pulmonary circulation to normal levels on the pulmonary leak index in patients suffering from severe ARDS.

Ethical review	Approved WMO
Status	Pending
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

Summary

ID

NL-OMON37462

Source
ToetsingOnline

Brief title
RELUF

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
acute respiratory distress syndrome, severe pulmonary disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ARDS, capillary shearstress, Circulation

Outcome measures

Primary outcome

pulmonary leak index

Secondary outcome

The titrating cardiac index to 2,5 to 3,5 l/min.m2 with a minimal SvO2 of 65%

on ventilator free days, use of rescue therapies and extravascular lung water

index, development of organ failure (SOFA), development of the lung injury

score.

Study description

Background summary

It is assumed that acute respiratory distress syndrome (ARDS) is an alveolar but also an endothelial disorder. Treatment modalities targeting alveolar disruption focus on low tidal volume ventilation and the avoidance of atelectasis and successfully decreased mortality. Activated protein C, heparin inhalation and corticosteroids targeted endothelial inflammation, but these therapies failed to reduce mortality.
ARDS is often accompanied by sepsis, which is characterized by a high cardiac output. A high cardiac output might cause endothelial shear stress in the lung, causing and/or aggravating ARDS. Experimental and retrospective data suggest that reducing lung capillary flow has a beneficial effect on gas exchange.

Study objective

To study the effect of reducing the pulmonary circulation to normal levels on the pulmonary leak index in patients suffering from severe ARDS.

Study design

open label, randomized controlled trial

Intervention

Titrating cardiac index to 2,5 -3,5 l/min.m2 with a minimal SvO2 of 65%.

Study burden and risks

Burden to the patient:
An (additional) arterial canule is placed in the femoral artery. Sedated patients (most of the patients suffering from severe ARDS are deeply sedated) have minimal burden during placement of this canule. Moreover, this canule can also function as a routine invasive arterial pressure monitoring tool. Also, it is possible to withdraw blood from this canule. This makes the standard invasive canullation superfluous. To measure the pulmonary leak index, a small amount of radioactive 67Ga will be given. The amount of radiation is considered minimal.

Risks:
Asthma bronchiale
Bradycardia
hypotension

All patients are admitted on the intensive care unit, in a extensive monitoring environment. The beta blocker that is used to down regulate cardiac index is esmolol, known for its very short half-life. If complication occur, beta blockade therapy is stopped and the complications will resolve.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

severe ARDS with a PaO2/FiO2 ratio < 100 mmHg

Exclusion criteria

patients having increased intracranial pressure
patients on inotropic support
Cardiac index >4 l/min.m2
history of bronchial hyper reactivity
Patients with a preterminal illness (active hematologic disease, metastatic malignancy*s)
Patients below 18 years or older than 85 years

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2012
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-10-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL37843.078.11