Low-flow extra-corporeal CO2 removal and 4 mL/kg tidal volume vs. 6mL/kg tidal volume to enhance protection from ventilator induced lung injury in acute lung injury: a randomized multi-center trial

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Lower tidal volumes in order to reduce VILI and days on the ventilator which will reduce the number of days on the ICU

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

Summary

ID

NL-OMON37536

Source
ToetsingOnline

Brief title
Enhance Lung Protection study

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Acute Respiratory Distress Syndrome; acute lung failure

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Dirinco,Hemodec,Hemodec en Dirinco

Intervention

Keyword: extracorporeal carbon dioxide removal (ECCO2-R), Low tidal volume, Ventilator induced lung injury (VILI)

Outcome measures

Primary outcome

Primary end-point:

- Number of ventilator-free days during the 28 days immediatly after

randomization.

Secondary outcome

Secondary end-point:

- 28-day all-cause mortality

- 90-day all-cause mortality

- Number of ICU-free days during the 28 days immediatly after randomization

- Cumulative incidence of first episode of refractory hypoxemia (first 28 days)

- Cumulative incidence of the use of rescue therapies

- Cumulative incidence of first day that meet criteria for weaning readiness

during 28 days after randomization

- Cumulative SOFA-free score between randomization and day 28

- Cumulatieve incidence of severe adverse events during 28 days after

randomization

Study description

Background summary

Acute Respiratory Distress Syndrome (ARDS) is characterized by acute onset of bilateral infiltrates on chest X-ray, pulmonary artery wedge pressure <18mmHg or absence of clinical evidence of high left atrial pressure, and a PaO2/FiO2 ratio =<200.
ARDS patienten do need mechanical ventilation, but this also causes damage to the lungs, this is called Ventilator induced Lung Injury (VILI). Since the ARDSnet trial (2000) it is known that ARDS patienten have a higher survival using low tidal volumes (6mL/kg), because this causes less damage.

By using even lower tidal volumes (4mL/kg) VILI will be reduced. Although the problem with such a small tidal volumes is the fact that carbon dioxide levels will increase in the blood. By using a DECAP machine the blood will be filtered extra-corporeal, using the dialyse concept.
Veneous blood will be transported to the DECAP device using a coaxial (two-way) catheter. The DECAP will wash-out the CO2 and pumps the blood through the catheter back to the patient. Using mechanical ventilation the blood will be oxygenated.

Study objective

Lower tidal volumes in order to reduce VILI and days on the ventilator which will reduce the number of days on the ICU

Study design

Patients will be randomized into two groups after informed consent.

Control group:
- Ventilation following the ARDSnet protocol
- Tidal volumes of 6mL/kg predicted body weight
- Oxygenation of 55-80 mmHg of SpO2 88-95%
- Plateau pressure <30 cm H2O
- Arterial pH 7.30-7.45

Intervention group:
- Tidal volumes of 4mL/kg predicted body weight
- Oxygenation 55-80 mmHg of SpO2 88-95%
- Plateau pressure =<25 cm H2O
- arterial pH 7.30-7.45
- ECCO2-R to remove CO2 from the blood

Intervention

Mechanical ventilation with lower tidal volumes (4mL/kg).

Connection to DECAP using a coaxiale (two-way) catheter, which will transport blood to and from the patient.

Study burden and risks

DECAP is based on the dialyse concept.
To avoid coagulation inside the system, the patient will receive heparine. Heparine will slow-down the coagulation which will increase the risk of bleedings.

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

- age > 18 years
- are on invasive assisted breathing less then 48 hours
- Less than 24 hours since diagnosis for ARDS: with PF<=200 and PEEP>=10, bilateral infiltrates on chest X-Ray and no clinical evidence of left artrial hypertension
- have a commitment to full support

Exclusion criteria

- Intubation and mechanical ventilation for > 48 hours
- risk of systemic bleeding with anticoagulation
- acute brain injury
- body mass index >40
- Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2012
Enrollment:	18
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-11-2012
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
ClinicalTrials.gov	NCT01522599
CCMO	NL39966.078.12