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Efficacy of positive end-expiratory pressure titration after the alveolar recruitment manoeuvre in patients with acute respiratory distress syndrome

Submission date
23/10/2008

Recruitment status
No longer recruiting

Registration date
31/10/2008

Overall study status
Completed

Last Edited
12/03/2010

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
In the acute respiratory distress syndrome (ARDS), the right level of positive end-expiratory pressure (PEEP) may decrease ventilator-induced lung injury by opening the lung and keeping it open. We evaluated whether setting the PEEP using decremental PEEP titration after alveolar recruitment manoeuvre (ARM) affects the clinical outcome in patients with ARDS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol was approved by the Institutional Board of the Ethics Committee of Asan Medical Center on the 14th August 2006 (ref: 2006-0286)

Study design
Randomised, controlled, single centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute respiratory distress syndrome (ARDS)

Interventions
Control group:
The FiO2-PEEP strategy has been used in previous ARDS Network studies. PEEP and FiO2 were set according to the table of lower PEEP/higher FiO2 combinations, with the goal of obtaining a lower PEEP level compatible with an oxygenation target.

Decremental PEEP titration group:
The alveolar recruitment manoeuvre (ARM) was performed immediately after enrolment in the study and was applied once a day in the morning for 1 week. After ARM, the decrease in PEEP was continued until a decrease of greater than 2% of the saturation from the previous SaO2 and drop of static compliance was identified (decremental PEEP titration).

Total duration of treatment: 1 week
Total duration of follow-up: from enrolment to leaving the hospital

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
28-day mortality

Secondary outcome measures
1. Duration of mechanical ventilation
2. Intensive Care Unit (ICU) stay
3. Use of paralysing or sedative agents

Measured until leaving the hospital.

Overall study start date
01/06/2004

Completion date
30/09/2006

Eligibility

Key inclusion criteria
1. Criteria of ARDS proposed by the American-European Consensus Conference:
1.1. Acute onset
1.2. Presence of hypoxaemia (arterial oxygen tension/fraction of inspired oxygen (FiO2) (PF ratio) less than 200 mmHg regardless of the PEEP level)
1.3. Bilateral and diffuse opacities seen on frontal chest X-ray film
1.4. Absence of left ventricular failure with pulmonary arterial occluded pressure less than 18 mmHg
2. Recruited into the trial within 48 hours of meeting above ARDS criteria
3. Aged 18 - 82 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 patients

Key exclusion criteria
1. Haemodynamic instability
2. Elevated intracranial pressure
3. High risk of mortality within 3 months from other than ARDS (severe organ failure, and cancer patients in terminal stages of the disease)
4. Refusal to participate

Date of first enrolment
01/06/2004

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
Korea, South

Study participating centre
Division of Pulmonary and Critical Care Medicine
Seoul
Korea, South
138-736

Sponsor information

Organisation
Asan Medical Center (South Korea)

Sponsor details
c/o Younsuck Koh
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Sponsor type
Hospital/treatment centre

Website
http://www1.amc.seoul.kr

ROR
https://ror.org/03s5q0090

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Asan Medical Center (South Korea) - the internal research fund of Intensive Care Units

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2009		Yes	No