

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	☐ Prospectively registered ☐ Protocol
Registration date 31/10/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/03/2010	Condition category Respiratory	☐ 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

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)

Primary study design

Interventional

Study design

Randomised, controlled, single centre study

Study type(s)

Treatment

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(s)

28-day mortality

Key secondary outcome(s)

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

Measured until leaving the hospital.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

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