

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

<b>Submission date</b> 23/10/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/10/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/03/2010	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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 FiO<sub>2</sub>-PEEP strategy has been used in previous ARDS Network studies. PEEP and FiO<sub>2</sub> were set according to the table of lower PEEP/higher FiO<sub>2</sub> 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 SaO<sub>2</sub> 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 (FiO<sub>2</sub>) (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?
<a href="#">Results article</a>	results	01/12/2009		Yes	No