

The clinical outcomes of using high frequency ventilation compared with conventional ventilation in children with severe respiratory failure

Submission date 14/03/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/10/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/10/2015	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Acute respiratory distress syndrome (ARDS) is a life-threatening medical condition where the lungs can't provide enough oxygen for the rest of the body. If someone develops ARDS, they are put on a mechanical ventilator to assist their breathing. High frequency oscillation ventilation (HFOV) is an alternative to conventional mechanical ventilation (CMV) to treat patients with severe ARDS. The aim of this study is to compare the effectiveness of HFOV and CMV in children with severe ARDS.

Who can participate?

Patients aged between 1 month and 15 years with a diagnosis of ARDS at King Chulalongkorn Memorial University Hospital.

What does the study involve?

Participants will be randomly allocated to be treated with either HFOV or CMV.

What are the possible benefits and risks of participating?

The results of this study will help us to identify groups of ARDS patients who can benefit from using either HFOV or CMV.

Where is the study run from?

King Chulalongkorn Memorial University Hospital (Thailand).

When is the study starting and how long is it expected to run for?

From March 2012 to February 2014.

Who is funding the study?

Ratchada Pisek Somphot Fund.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
The clinical efficacy of high frequency ventilation compared with conventional ventilation with lung volume recruitment in severe pediatric acute respiratory distress syndrome: a randomized controlled trial

Acronym
HFCV-PEARDS

Study objectives
To determine the efficacy of lung volume recruitment maneuver (LVRM) with high frequency oscillatory ventilation (HFOV) and continuous mandatory ventilation (CMV) on oxygenation, hemodynamic alteration and clinical outcome in children with severe acute respiratory distress syndrome (ARDS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee at King Chulalongkorn University, 30/03/2012, ref: 154/55

Study design
Randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute respiratory distress syndrome

Interventions

We performed a randomized controlled trial enrolling pediatric patients (aged 1 month to 15 years from March 2012 to September 2014) who were diagnosed to have severe ARDS upon PICU admission. Informed consent was obtained from the parents prior to their evaluation for HFOV therapy. Before randomization to the treatment arms, all patients were received CMV with the FiO₂ of 1, the median PEEP of 12 cmH₂O, fluid resuscitation to keep high CVP (range between 8-12 mmHg) and were mostly on either inotropics or vasopressors at the time of LVRM with either CMV or HFOV. All patients were deeply sedated and paralyzed. Patients were randomized to the LVRM protocol combined with either HFOV or CMV. Baseline characteristic data, oxygenation, hemodynamic parameters and clinical outcomes were recorded during the procedure and at 1, 4, 12, 24, 48 and 72 hours after LVRM.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Oxygenation response, PaO₂/FiO₂, Oxygen index, A-a gradient compare Pre-post lung volume recruitment. Timepoints: baseline, 1 hour, 2 hours, 3 hours, 6 hours and 24 hours after lung volume recruitment.

Key secondary outcome(s)

1. Duration of PICU stay
2. Morbidity/mortality in PICU

Completion date

01/12/2014

Eligibility

Key inclusion criteria

Patients aged >1 month and <15 years with a diagnosis of ARDS from the PICU at King Chulalongkorn Memorial University Hospital

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 months

Upper age limit

15 years

Sex

All

Key exclusion criteria

1. Evidence/suspicion of congestive heart failure
2. Evidence of left atrial hypertension
3. Severe irreversible neurological injury or Intractable shock
4. The underlying disease was deemed irreversible or ARDS > 48 hours
5. Pre-existing air leak syndrome (e.g., pneumothorax or pneumomediastinum) or pre-existing cystic lung disease

Date of first enrolment

03/03/2012

Date of final enrolment

01/09/2014

Locations**Countries of recruitment**

Thailand

Study participating centre

King Chulalongkorn University Hospital

Bangkok

Thailand

10330

Sponsor information**Organisation**

King Chulalongkorn Memorial Hospital

ROR

<https://ror.org/05jd2pj53>

Funder(s)

Funder type

Research organisation

Funder Name

Ratchada Pisek Somphot Fund (Thailand)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Other