

The use of high frequency oscillator ventilation (HFOV) in paediatric acute respiratory distress syndrome (ARDS) with open lung technique

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		<input type="checkbox"/> Protocol
Registration date 07/09/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/09/2009	Condition category Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

The use of high frequency oscillator ventilation (HFOV) in paediatric acute respiratory distress syndrome (ARDS) with open lung technique: a prospective, interventional open label trial

Study objectives

To determine the efficacy and feasibility of high frequency oscillator ventilation (HFOV) in children with acute respiratory distress syndrome (ARDS) by using HFOV combined with an open lung technique.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Thailand, on the 5th April 2007 (ref: 236/2007; REC NO 002/50)

Study design

Prospective interventional open label trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Paediatric acute respiratory distress syndrome (ARDS)

Interventions

Recruitment protocol:

Body weight less than 35 kg (use of 3100 A):

1. Select patient (central line and/or arterial lines were placed prior to the manoeuvre)
2. Stable VS (optimised preload/use of inotrope) were required in all patients enrolling in the study. Start initial setting of HFOV, FiO₂ 1, MAP 30 cmH₂O (turn piston off), 20 secs then gradually weaned MAP down to 5 - 8 cmH₂O above previous conventional ventilator MAP (keep oxygen sat greater than 92%).

Body weight greater than 35 kg (use of 3100B):

1. Select patient (central line and/or arterial line were placed prior to the recruitment manoeuvre)
2. Stable VS (optimised preload/use of inotrope/vasopressor) were required. Start initial setting of HFOV, FiO₂ 1, MAP 35 cmH₂O (turn piston off), 30 seconds then gradually wean MAP down to 5 - 8 cmH₂O above conventional ventilator. (Consider stopping procedure if unstable VS, BP drop and cannot correct by volume resuscitation or inotrope titration). The RMs can be repeated but not more than twice/day during the first 3 days if FiO₂ could not weaned down more than 0.6, other ventilator adjustment was followed by the HFOV operation protocol.
3. If patients failed to keep oxygen saturation above 95% on the first trial of RM, repeat RM with raised mPaw to +3 cmH₂O above the previous mPaw followed by weaning down the mPaw gradually every 3 - 5 minutes until it reached 5 - 8 cmH₂O above the previous CV mPaw or the oxygen saturation start to drop below 95%. The RM will be done only in the first three days.

Body weight less than 35 kg (use of 3100 A):

1. Select patient (central line and/or arterial line were placed prior to the recruitment manoeuvre)
2. Stable VS (optimised preload/use of inotrope) were required. (Consider stopping procedure if unstable VS, BP drop and could not correct by volume resuscitation or inotrope titration). The RMs were repeated but not more than twice/day during the first 3 days if FiO₂ could not wean down more than 0.6, other ventilator adjustment were followed by HFOV our operation protocol. Also blood samples were collected at baseline, 1 hour after initial RM procedure and 24 hours thereafter.
3. Adjust other ventilator settings and wean were followed HFOV protocol or per PICU attendings.
4. The patients were switched back to CV mode if mPaw stay in the range of 22 - 24 cmH₂O, on FiO₂ equalling 0.4, or on HFOV greater than 24 hours and have overall clinical stable for more than 24 hours.
5. The patients were placed back on HFOV if intolerance to CV, e.g. oxygen saturation less than 88% was more than 15 minutes (FiO₂ greater than 0.6) or Ph less than 7.3 and by greater than 0.1 from last HFOV value.

Use of high frequency oscillator ventilation with open lung technique for the first three days.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Oxygenation response, measured at 28 days in PICU

Key secondary outcome(s)

Mortality, measured at 28 days in PICU

Completion date

31/12/2008

Eligibility

Key inclusion criteria

1. Paediatric patients aged greater than 1 month to less than 15 years old (from January 2007 - November 2008), either sex
2. Diagnosis of ARDS within 72 hours of Paediatric Intensive Care Unit (PICU) admission
3. No exclusion criteria

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. Pulmonary capillary wedge pressure greater than or equal to 18 mmHg
2. Evidence of left atrial hypertension
3. Severe irreversible neurological injury or intractable shock
4. The underlying disease was deemed irreversible or ARDS greater than 48 hours
5. Pre-existing air leak syndrome (e.g., pneumothorax or pneumomediastinum)
6. Pre-existing cystic lung disease

Date of first enrolment

01/01/2007

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Thailand

Study participating centre

King Chulalongkorn Memorial Hospital

Bangkok

Thailand

10330

Sponsor information

Organisation

Rachada Pisek Somphotch (Thailand)

Funder(s)

Funder type

Industry

Funder Name

Rachada Pisek Somphotch (Thailand) - Local University Fund

Funder Name

Viasys Healthcare (Thailand)

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

Not provided at time of registration