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

Submission date 21/08/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/09/2009	**Overall study status** Completed	
Last Edited 08/09/2009	**Condition category** Respiratory	

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
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 N0 002/50)

Study design
Prospective interventional open label trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Paediatic 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 manouevre)
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 manouevre)
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 manouevre)
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 measure
Oxygenation response, measured at 28 days in PICU

Secondary outcome measures
Mortality, measured at 28 days in PICU

Overall study start date
01/01/2007

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

Age group
Child

Lower age limit
1 Months

Upper age limit
15 Years

Sex
Both

Target number of participants
20 - 30 patients

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
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Sponsor information

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Sponsor type
University/education

Funder(s)

Funder type
Industry

Funder Name
Rachada Pisek Somphotch (Thailand) - Local University Fund

Funder Name
Viasys Healthcare (Thailand)

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