ISRCTN64665281 https://doi.org/10.1186/ISRCTN64665281

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

Registration date
19/10/2015

Overall study status
Completed

Last Edited
19/10/2015

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
Prof Rujipat Samransamruajkit
rujipatrs@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Rujipat Samransamruajkit

Contact details
Pediatric Critical Care Division
Department of Pediatrics
King Chulalongkorn Memorial Hospital
Bangkok
Thailand
10330
+66 (0)2 256 4951
Rujipat.S@chula.ac.th

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

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

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 measure
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.

Secondary outcome measures
1. Duration of PICU stay
2. Morbidity/mortality in PICU

Overall study start date
03/03/2012

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

Age group
Child

Lower age limit
1 Months

Upper age limit
15 Years

Sex
Both

Target number of participants
20

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

Sponsor details
1873 Rama 4 Road
Bangkok
Thailand
10330
+66 (0)2 256 4951
Rujipat.S@chula.ac.th

Sponsor type
University/education

ROR
https://ror.org/05jd2pj53

Funder(s)

Funder type
Research organisation

Funder Name
Ratchada Pisek Somphot Fund (Thailand)

Results and Publications

Publication and dissemination plan
The article has been submitted for publication.

Intention to publish date
05/10/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Other