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Assessment of lung water in patients with low blood pressure after infection

Submission date	Recruitment status	[_] Prospectively registered
16/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/02/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/10/2018	Circulatory System	

Plain English summary of protocol
Background and study aims
Extravascular lung water refers to fluid within the lung. Increase in extravascular lung water is associated with death in very ill patients. The purpose of this study is to compare three methods of lung ultrasound with transpulmonary thermodilution technique.

Who can participate?
Individuals with septic shock, 18 years old or over

What does the study involve?
All patients will be assessed with three methods of lung ultrasound (total B-line scores, BLUE points and scanning eight regions) and the results will be compared with the transpulmonary thermodilution technique.

What are the possible benefits and risks of participating?
A benefit is improvement in the monitoring of the patients. The risks are bleeding, haematoma and pneumothorax.

Where is the study run from?
Phramongkutklao Hospital (Thailand)

When is study starting and how long is it expected to run for?
From March 2013 to July 2014

Who is funding the study?
Phramongkutklao Hospital Foundation Under Her Royal Highness Princess Maha Chakri Sirindhorn Patronage (Thailand)

Who is the main contact?
Dr. Pattarin Pirompanich

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparison of three methods of lung ultrasound with the transpulmonary thermodilution technique for assessment of extravascular lung water in patients with septic shock

Study objectives
Extravascular lung water index greater than 10 mL/kg in patients with cardiogenic pulmonary oedema correlates with pulmonary capillary wedge pressure of greater than 20 mm Hg. Measurement of extravascular lung water needs sophisticated tools and use of the invasive transpulmonary thermodilution technique. By contrast, multiple B-lines by transthoracic portable ultrasound have been recently proposed to correlate with increased extravascular lung water in patients with cardiogenic pulmonary oedema.

Lung ultrasound has a good correlation with transpulmonary thermodilution technique for the assessment of extravascular lung water in patients with septic shock.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board of the Royal Thai Army Medical Department, 22/04/2009
Reference number: R032h/56

Study design
Cross sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Septic shock

Interventions
1. Total B-line scores
2. BLUE points
3. Scanning eight regions
These three methods of lung ultrasound were used on each patient to assess extravascular lung water and the results were compared with those from obtained with the transpulmonary thermodilution technique.

Intervention Type
Device

Primary outcome measure
Best method of lung ultrasound to diagnose pulmonary oedema in patients with septic shock: cutoff point of extravascular water index measured by transpulmonary thermodilution greater than
10 mL/kg predicted bodyweight, which is correlated with a pulmonary capillary wedge pressure of greater than 20 mmHg to indicate pulmonary oedema

Secondary outcome measures
Cutoff point of total B-line scores to predict extravascular lung water index of 10 mL/kg or more

Overall study start date
01/03/2013

Completion date
30/07/2014

Eligibility

Key inclusion criteria
1. Age 18 years old or over
2. Septic shock requiring central venous catheterisation and arterial catheterisation for continuous pressure monitoring

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 comparisons from 17 patients

Key exclusion criteria
1. Valvular heart disease
2. Pregnancy
3. Acute or history of pulmonary embolism
4. Lung resection surgery
5. Acute respiratory distress syndrome
6. Interstitial lung diseases
7. Mulitilobar pneumonia
8. Pleural diseases

Date of first enrolment
01/09/2013

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
Thailand

Study participating centre
Phramongkutklao Hospital
315 Phayathai Road
Ratchathewi
Bangkok

Thailand
10400

Sponsor information

Organisation
Phramongkutklao Hospital Foundation Under Her Royal Highness Princess Maha Chakri Sirindhorn Patronage

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Sponsor type
Charity

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Funder(s)

Funder type
Charity

Funder Name
Phramongkutklao Hospital Foundation Under Her Royal Highness Princess Maha Chakri Sirindhorn Patronage

Results and Publications

Publication and dissemination plan
Publish the results in a few months

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2018		Yes	No