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Can transthoracic echocardiography predict fluid responsiveness in shock after a mini-fluid challenge?

Submission date 26/11/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/12/2013	**Overall study status** Completed	
Last Edited 11/07/2017	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Fluid responsiveness is defined as the ability of the heart to pump more blood in response to fluid administration. Accurate real-time assessment of fluid responsiveness is an important clinical goal. The aim of this study is to find out whether echocardiography (a heart ultrasound scan) can be used predict fluid responsiveness in patients with shock following a low-volume infusion.

Who can participate?
Mechanically ventilated adults with shock (low blood flow to tissues)

What does the study involve?
In all participants echocardiography is performed during a 50 ml fluid infusion over 10 seconds and a further 450 ml over 15 min. The amount of blood pumped by the heart (cardiac output) is recorded. Patients are classified as responders if cardiac output increases by at least 15% following the fluid administration.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Affiliated Provincial Hospital of Anhui Medical University (China)

When is the study starting and how long is it expected to run for?
March to October 2013

Who is funding the study?
Investigator initiated and funded (China)

Who is the main contact?
Mrs Yunfan Wu

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Can transthoracic echocardiography predict fluid responsiveness in shock after 50 ml crystal solution over 10 seconds? A mini-fluid challenge study

Study objectives
The trialists hypothesize that a small fluid preload and faster infusion rate can also predict responsiveness. This study aimed to determine whether echocardiographic parameters following a 50 ml infusion of crystalloid solution over 10 s can predict fluid responsiveness in critically ill patients with hypovolemic or septic shock.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethics Committee of Anhui Provincial Hospital, 29/03/2013

Study design
Prospective trial

Primary study design

Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Hypovolemic or septic shock

Interventions
The study will involve 55 mechanically ventilated adults with hypovolemic or septic shock. The attending physician clinically determined the need for volume expansion (VE). If patients were treated with norepinephrine, the dose remained unchanged from before VE until all hemodynamic measurements were complete.

Echocardiography was performed during a 50 ml infusion of crystalloid solution over 10 s and a further 450 ml over 15 min. Cardiac output (CO), stroke volume (SV), aortic velocity time index (VTI), and left ventricular ejection fraction (LVEF) were recorded. Echocardiographic parameters were measured using a bedside Phillips IU22 xMATRIX ultrasound system (Royal Philips Electronics; Amsterdam, the Netherlands) with a 3-5 MHz phased-array probe. M-mode (time-motion) echocardiography was employed at the level of the aortic annulus in a two-dimensional view from the parasternal long-axis window. The aortic diameter (D), left ventricular end-diastolic diameter, left ventricular end-systolic diameter and heart rate (HR) were measured. Using the in-built software, the left ventricular end-diastolic volume (LEDV) and left ventricular end-systolic volume (LESV) were determined. In addition, heart rate, blood pressure, CVP and other hemodynamic parameters were recorded throughout the study. Aortic blood flow and velocity time integral (VTI) were obtained from an apical five-chamber view.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Cardiac output (CO)
2. Stroke volume (SV)
3. Aortic velocity time index (VTI)
4. Left ventricular ejection fraction (LVEF)

Secondary outcome measures

Area under the receiver operating characteristic curves (AUC) compared CO variations after 50 ml over 10 s (ΔCO50) and 500 ml over 15 min (ΔCO500) and the variation of VTI after infusion of 50 ml fluid over 10 s (ΔVTI50)

Overall study start date
01/03/2013

Completion date
31/10/2013

Eligibility

Key inclusion criteria
1. Evidence of inadequate tissue perfusion with acute circulatory failure defined as a systolic arterial pressure of 90 mmHg (or a decrease of 40 mmHg in a patient with hypertension)
2. Urine output below 0.5 ml/kg/h for over 1 h
3. Tachycardia (heart rate < 100/min)
4. Mottled skin
5. Clinical diseases of hypovolemic or septic shock associated with a systemic inflammatory response syndrome
6. Septic shock
7. Controlled massive hemorrhage
8. The attending physician clinically determined the need for volume expansion (VE)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
55

Key exclusion criteria
1. Age < 18 years
2. Moribund
3. Cardiomyopathy
4. Pulmonary edema
5. Increased intracranial pressure
6. Pregnancy
7. Active bleeding
8. Atrial fibrillation
9. Cardiac arrhythmias
10. Myocardial ischemia or infarction within 1 month before the study

Date of first enrolment

01/03/2013

Date of final enrolment
31/10/2013

Locations

Countries of recruitment
China

Study participating centre
Affiliated Provincial Hospital of Anhui Medical University
Hefei
China
230001

Sponsor information

Organisation
Affiliated Provincial Hospital of Anhui Medical University (China)

Sponsor details
Department of Critical Care Medicine
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230001

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03n5gdd09

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (China)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/05/2014		Yes	No