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Predicting fluid responsiveness using the mini fluid challenge and pulse contour cardiac output measurements

Submission date
21/07/2015

Recruitment status
No longer recruiting

Registration date
04/08/2015

Overall study status
Completed

Last Edited
12/05/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Critically ill patients often require fluid therapy to improve circulation. However, only 50% of the patients respond to this fluid therapy. Too much fluid (fluid overload)can be harmful and can contribute to death and disease (morbidity and mortality). To prevent fluid overload in critically ill patients, the mini-fluid challenge can be used. This involves giving each patient a minimal amount of fluid. The patients hemodynamic response to this fluid (for example, the amount of blood being pumped from the heart (cardiac output)and blood pressure)are measured and this response is then used to predict a response to future and further fluid loading. Pulse contour cardiac output methods can predict hoe a patient will respond to being given fluid by providing cardiac output (CO) measurements. The mini-fluid challenge may predict fluid responsiveness with minimum risk of fluid overloading. However, the amount of fluid needed and how best to evaluate the effect of giving it are both unclear. In this study, we therefore studied two pulse contour CO methods in predicting fluid responsiveness using a minimum volume in mini fluid challenges, in critically ill patients.

Who can participate?
Adult patients being mechanical ventilated after heart surgery.

What does the study involve?
Patients are given 10 intravenous doses of 50 mL of fluid (hydroxyethyl starch), resulting in a total of 500 mL being given to each patient. Cardiac output is assessed by various measurements (Modelflow R (FMS, COm) and PulseCOR (LiDCO, COli)) just before each dose and then one minute afterwards.

What are the possible benefits and risks of participating?
There is additional hemodynamic monitoring that gives no additional risks or benefits compared to a standard intensive care treatment.

Where is the study run from?
Leiden University Medical Center, Leiden (The Netherlands)

When is the study starting and how long is it expected to run for?
December 2001 to December 2014

Who is funding the study?
Department of Intensive Care Medicine, Leiden University Medical Center (The Netherlands)

Who is the main contact?
Dr B. F Gerts

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P01.111

Study information

Scientific Title
Predicting fluid responsiveness using the mini fluid challenge and pulse contour cardiac output measurements : a prospective interventional study

Study objectives
The hypothesis of the current study is that a more accurate CO measurement technique can lower the amount of fluid that is needed to predict fluid responsiveness by mini challenges. We therefore study two pulse contour CO methods in predicting fluid responsiveness using a minimum volume in mini fluid challenges, in critically ill patients after cardiac surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Medical Ethics Committee, Leiden University Medical Center, Leiden, the Netherlands, 28/01/2002, ref: P01.111

Study design
Prospective interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Postoperative mechanically ventilated cardiac surgery patients

Interventions
In each patient, a total of 10 consecutive 50 mL fluid boluses with hydroxyethyl starch solution were administered intravenously. Basic heamodynamic maesurements and cardiac output (CO) were registered, using two different arterial waveform (i.e. pulse contour) methods; modified ModelflowR (COm, FMS, Amsterdam, the Netherlands) and PulseCOR (COli from LiDCO Ltd., London, UK).

Intervention Type
Procedure/Surgery

Primary outcome measure
The area under the curve, positive and negative predictive value of COm and COli for the prediction of fluid responsiveness.

Secondary outcome measures
Predictive capabilities of mini fluid challenges from 50 to 500 ml.

Overall study start date
01/12/2001

Completion date
01/12/2014

Eligibility

Key inclusion criteria
Patients undergoing elective coronary artery bypass grafting or valve repair

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
21

Total final enrolment
21

Key exclusion criteria
1. Previous myocardial infarction
2. Congestive heart failure
3. Aortic aneurysm
4. Extensive peripheral arterial occlusive disease
5. Postoperative valvular insufficiency
6. Artificial pacing and use of a cardiac assist device

Date of first enrolment
01/05/2006

Date of final enrolment
01/03/2011

Locations

Countries of recruitment
Netherlands

Netherlands Antilles

Study participating centre
Leiden University Medical Center
Albinusdreef 2
Leiden
Netherlands
2333ZA

Sponsor information

Organisation
Department of Intensive Care Medicine, Leiden University Medical Center

Sponsor details
Albinusdreef 2
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Sponsor type
University/education

ROR
https://ror.org/05xvt9f17

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Intensive Care Medicine, Leiden University Medical Center

Results and Publications

Publication and dissemination plan
We plan to publish the results in a peer reviewed journal

Intention to publish date
01/01/2015

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		01/05/2018	12/05/2021	Yes	No