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Central venous pressure variation

Submission date	Recruitment status	[_] Prospectively registered
09/06/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/06/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/05/2021	Circulatory System	

Plain English summary of protocol

Background and study aims
Fluids are frequently given to patients who have undergone cardiac surgery to improve their circulation. However, only 50% of patients respond to fluid administration and it is not easily to predict which patient will be a "fluid-responder". To make matters worse, giving too little or too much fluid can have harmful effects. The variation in the arterial blood pressure caused by mechanical ventilation has shown to help in the prediction of "fluid-responsiveness". More simply put; if the arterial blood pressure shows a marked change during inspiration (breathing in) and expiration (breathing out), this could indicate a relative underfilling of the circulation (i.e. less fluid in the circulation) and the patient is more likely to respond to fluid administration, where if the arterial blood pressure would remain unaltered this would likely not be the case. However, a good functioning arterial catheter is necessary to detect these changes. We want to find out if changes in the "venous blood pressure" induced by mechanical ventilation is also a good predictor of "fluid-responsiveness", which requires a central venous catheter.

Who can participate?
Cardiac surgery patients treated in intensive care and mechanically ventilated.

What does the study involve?
Patients who have undergone cardiac surgery are standard equipped with an arterial and central venous catheter and therefore we can investigate in this patient group if the venous blood pressure variations can predict the response upon a fluid administration of 500cc compared to the arterial blood pressure variation. If so, then physicians have another tool to guide patient-tailored fluid administration. Besides from the administration of 500cc of fluids, no additional interventions are performed in this study other than standard care after surgery.

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

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

Who is the main contact?
Dr Thomas Cherpanath

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
Central venous pressure variation: a prospective interventional study

Study objectives
Ventilator-induced central venous pressure variation is able to predict fluid responsiveness

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
Stroke volume variation and pulse pressure variation were measured with pulse contour analysis using an arterial catheter, while central venous pressure variation was obtained from a central venous catheter.

Intervention Type
Procedure/Surgery

Primary outcome measure
Correlation, sensitivity and specificity of central venous pressure variation in the prediction of fluid responsiveness.

Secondary outcome measures
Accuracy of central venous pressure variation in comparison to stroke volume variation and pulse pressure variation.

Overall study start date
01/12/2001

Completion date
01/12/2014

Eligibility

Key inclusion criteria
Elective cardiac surgery patients postoperatively on the Intensive Care Unit who are mechanically ventilated with tidal volumes of 8-10 mL/kg without spontaneous breathing efforts or cardiac arrhythmia.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Total final enrolment
19

Key exclusion criteria
1. Previous myocardial infarction
2. Congestive heart failure
3. Extensive peripheral arterial occlusive disease
4. Severe arrhythmia
5. Use of a cardiac assist device
6. Artificial pacing, postoperative valvular insufficiency or presence of spontaneous breathing during mechanical ventilation

Date of first enrolment
01/05/2006

Date of final enrolment
01/03/2011

Locations

Countries of recruitment
Netherlands

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
Leiden
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2333ZA

Sponsor type
University/education

Website
www.lumc.nl

ROR
https://ror.org/05xvt9f17

Funder(s)

Funder type
Not defined

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		01/11/2016	10/05/2021	Yes	No