Central venous pressure variation

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

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

Dr Thomas Cherpanath

ORCID ID

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

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

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes