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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
Dr B.F. Geerts

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# Additional identifiers

### Protocol serial number
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

### Primary study design
Interventional

### Study design
Prospective interventional study

### Study type(s)
Diagnostic

### 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(s)
The area under the curve, positive and negative predictive value of COm and COli for the prediction of fluid responsiveness.

### Key secondary outcome(s)
Predictive capabilities of mini fluid challenges from 50 to 500 ml.

### Completion date
01/12/2014

## Eligibility

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

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Total final enrolment

### 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

### 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
Hospital/treatment centre

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