Mean systemic filling pressure and heart performance as predictors of successful fluid responsiveness in patients with surgical aortic valve replacement.

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Predicting fluid responsiveness during PLR and fluid challenge (FC) by changes in (Pms).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON40019

Source
ToetsingOnline

Brief title
Mean systemic filling pressure predictor fluid responsiveness AVR

Condition

- Other condition
- Cardiac valve disorders

Synonym
Hemodynamics

Health condition

Hemodynamica

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Catharina Ziekenhuis

Intervention

Keyword: Mean systemic filling pressure

Outcome measures

Primary outcome

PLR, followed by FC of 500mL Ringers Lactate.

Secondary outcome

Niet van toepassing

Study description

Background summary

The assessment of the cardiovascular state in critically ill patients is subject to difficulties in terms of the fact that several hemodynamic parameters, for example mean arterial blood pressure (MAP) and cardiac output (CO) supply insufficient information about the circulating volume and cardiac performance. There is a clinical need to adequate determination of intravascular volume status and therefore reliable predictors of fluid responsiveness are highly relevant. However, in determining the fluid status of a patient, the lack of appreciation of the venous side of the circulation persists today, which is greatly due to the inability to appropriately assess the venous side of the circulation. The importance of the venous part of the circulation is moreover reflected by the fact that an increase in venous resistance does reduce CO many times more than a similar increase in arterial resistance. Mean systemic filling pressure (Pms), which is defined as the pressure equal to the pressure which would be measured if the heart should suddenly stop pumping and all (arterial and venous) the pressures in the entire circulatory system should be brought to equilibrium instantaneously, is a good, complete and reliable reflection of the total intravascular fluid compartment. Passive leg raising (PLR) represents a *self-volume challenge* that predicts preload responsiveness and the transient hemodynamic changes on venous return can be directly monitored in ventilated patients, provided that there is an

intact circulation, in order to test the amount of volume responsiveness.

Study objective

Predicting fluid responsiveness during PLR and fluid challenge (FC) by changes in (Pms).

Study design

Prospective, observational study

Study burden and risks

Additional bleeding risk due to puncture of femoral artery instead of radial artery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Aortic valve replacement, low cardiac output due to low volume state

Exclusion criteria

Assist devices, arrhythmia

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-09-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	05-08-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL42108.060.12