Stroke volume variation derived from uncalibrated pressure waveform analysis for the prediction of fluid responsiveness in cardiac surgical patients with impaired left ventricular function

Published: 17-06-2008
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The aim of the study is to investigate the accuracy of this new cardiac output monitoring system in predicting fluid responsiveness.

Ethical review	Not approved
Status	Will not start
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON32328

Source
ToetsingOnline

Brief title
SVV as a predictor for fluidresponsiveness.

Condition

- Heart failures

Synonym
Prediction of fluid responsiveness

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac surgery patients, fluid responsiveness, impaired left ventricular function, stroke volume variation

Outcome measures

Primary outcome

Monitoring of cardiac output, bloodpressure, heart rate and stroke volume

variation before and after the administration of 7 ml/kg hydroxyethyl starch 6%

in patients in the operating theatre and the intensive care.

Secondary outcome

not applicable

Study description

Background summary

Adequate circulation of blood is dependent of cardiac function and preload: the amount of blood present in the circulation. The better cardiac function and the more blood present in the circulation, the better will be tissue oxygenation, up to a specific maximum. Howver, lessa blood in the ciculation cause a decrease in tissue oxygenation, and in mechanically ventilated patients in an increased pulse pressure variation and stroke volume variation. Stroke volume variation can be measured with a new, recently validated cardiac function monitor using invasive arterial pulse pressure contour analysis. Variation in blood pressure is measured as pulse pressure variation, whereas variation in stroke volume is measured as stroke volume variation. The administraion of intravenous fluids can cause an improved bloodcirculation. However, in patients with a decreased left ventricular function, fluid administration may cause decompensation.

Study objective

The aim of the study is to investigate the accuracy of this new cardiac output monitoring system in predicting fluid responsiveness.

Study design

This is a multicentre trial. Included are patients scheduled for cardiac surgery with a decreased left ventricular function. 25 patiënts in the UMC-Utrecht and 25 patiënts in the University Hospital in Aachen Germany. Excluded are patients with tachyarrhythmias, central intracardiac shunting, and children. Informed consent will be obtained during the pre-operative screening in teh days before surgery.
Maximum observation will be 8 hours. The used catheters will stay in situ as long as it is indicated, or will be removed if there is a contra-indication for it (i.e. infection). Data will be obtained and saved anonymously. Data analysis will be performed according to normal statistical procedures in the department of peri-operative and emergency care.

Study burden and risks

According to a protocol for monitoring cardiac surgery patients with a severely decreased left ventricular function, a pulmonary artery catheter will be placed as a standard peri-operative monitoring technique. Thereby, it is usual to administer an peripheral artery line in the radial artery. However, when we do not succed in placing this radial artery line, the femoral artery in the groin will be used. For this research, all patients will have an arterial line in a femoral artery. There is no extra change for harm besides the normal wellknown complications of administering intravascular catheters.

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

34 elective cardiac surgical patients with a left ventricular ejection fraction < 35% will be included in each center.

Exclusion criteria

Excluded will be patients with major vascular diseases (aortic aneurysm and or peripheral arterial vascular surgery), intracardiac shunts, esophageal dysfunction, and patients undergoing emergency surgery.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start

Enrollment:	34
Type:	Anticipated

Ethics review

Not approved

Date:	17-06-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL23414.041.08