Prediction and monitoring of cardiac response to intravenous fluid administration by non-invasive measurement of the initial systolic time interval after cardiac surgery

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The objective of the study is to develop a non-invasive method to optimize the assessment of cardiac preload and therapeutic fluid administration after coronary artery bypass surgery.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON33850

Source
ToetsingOnline

Brief title
Cardiac fluid response and ISTI measurement

Condition

- Coronary artery disorders

Synonym
coronary artery disease, heart monitoring

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cardiac monitoring, coronary artery bypass surgery, intensive care unit

Outcome measures

Primary outcome

The study parameters are: PEP and the respiratory change delta-PEP, ISTI and

delta-ISTI and cardiac output CO.

Secondary outcome

None

Study description

Background summary

Intravenous fluid administration is universally accepted as a treatment for hypotension after cardiac surgery. The accuracy of indexes, used to assess preload and predict fluid responsiveness, has been questioned, however. Parameters, able to unmask preload deficiency and to predict an improvement in cardiac function with volume expansion, are actively searched.

Study objective

The objective of the study is to develop a non-invasive method to optimize the assessment of cardiac preload and therapeutic fluid administration after coronary artery bypass surgery.

Study design

The study concerns the evaluation of a method of measurement by comparison with other methods. Thirty-five patients who are administered to the Intensive Care Unit after coronary artery bypass surgery and who are presumably hypovolaemic will be measured during administration of 2x250 ml of an isosmotic colloidal fluid solution, which is part of their standard treatment. From the

electro-cardiogram (ECG), arterial pressure Pa and impedance cardiogram (ICG) the parameters preejection period (PEP) and the respiratory change (delta) in PEP (delta-PEP), the initial systolic time interval (ISTI) and the respiratory change (delta-ISTI) will be determined before and after each administration of 250 ml of the fluid solution. These measures will be compared with the simultaneous cardiac output (CO), obtained by a standard thermodillution technique.

Study burden and risks

An additional number of four electrodes, similar to ECG-electrodes, will be attached to the patient. A small electrical current of 0.3 mArms will be transmitted through the thorax applied by the two outer electrodes, having a frequency of 64 kHz. The frequency of this current is well above the range of biological excitation and the amplitude is well below the range of biological excitation or sensing. The method is safe to be used on the intensive care unit. The method is non-invasive. Participating in the study contains no burden and no risk for the subjects. The nature or duration of the treatment will not change.

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

Intensive-care patients who are presumably hypovolaemic and who have a clinical reason for fluid administration.

Exclusion criteria

Younger than 18 or older than 80 years of age; medical, practical or ethical drawbacks or objections to participate. Blood loss by bleeding at a rate of over 100 ml/h. Relevant alterations in inotropic and vasopressor medication.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-08-2009
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	09-07-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL24735.029.08