FLuid responsiveness prediction using EXtra systoles

Published: 17-11-2016
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To determine whether analysis of extra systoles can predict fluid responsiveness

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON43262

Source
ToetsingOnline

Brief title
FLuid responsiveness prediction using EXtra systoles

Condition

- Coronary artery disorders

Synonym
coronary artery bypass graft, systolic blood pressure

Research involving
Human

Sponsors and support

Primary sponsor: anesthesiologie- onderzoeksbureau
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: extra systole, fluid responsiveness

Outcome measures

Primary outcome

To investigate if post-ectopic induced changes in blood pressure before a fluid bolus (5 ml/kg) predicts the fluid induced change in cardiac stroke volume

Secondary outcome

To investigate a mini fluid challenge*s effect on blood pressure and to investigate if mini fluid challenge induced changes in hemodynamic variables and in trans-oesophageal echocardiographic variables can predict how fluid bolus induce changes in cardiac function.

Study description

Background summary

In this study, we propose to investigate a novel technique for fluid responsiveness prediction. It is based on the occurrence of an extra systole, which induces a preload variation: Extra systoles are comprised by, first, the premature/ectopic beat with decreased cardiac preload, then, the post-ectopic beat with moderately increased preload. Consequently, the post ectopic beat is associated with a Frank-Starling curve right shift but is otherwise a normal sinus beat. As such, the post-ectopic beat elucidates and predicts the hemodynamic effect of increasing preload, i.e. giving fluids

Study objective

To determine whether analysis of extra systoles can predict fluid responsiveness

Study design

Interventional prospective study

Study burden and risks

The structured observations prior to and during a fluid bolus is the only

intervention in this study.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients requiring elective CABG or OPCAB surgery
- Patient*s age >= 18 years

Exclusion criteria

- Patient refusal
- Pregnancy

- EF < 35%
- End stage kidney failure (defined by the need for haemodialysis)
- Patients with atrial fibrillation or frequent and coupled extra systoles (e.g. trigemini)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	17-11-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL58966.042.16