Perioperative maintenance of global tissue perfusion and volemic state in abdominal surgery: Nexfin cardiac output and pulse pressure variation versus arterial blood pressure-guided therapy

Published: 28-09-2011
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Primary objective:Does perioperative maintenance of cardiac output and pulse pressure variation result in an overall reduction in postoperative complications when compared to arterial blood pressure-guided perioperative hemodynamics in patients...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON37876

Source
ToetsingOnline

Brief title
COGUIDE study

Condition

- Gastrointestinal therapeutic procedures

Synonym
Abdominal surgery, bowel surgery

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: Abdominal surgery, Fluid overload, Hemodynamics, Volume therapy

Outcome measures

Primary outcome

Main study endpoints: The primary endpoint is defined as postoperative

morbidity based on the incidence of a number of predefined complications until

30 days after surgery. These parameters include, among others, reoperation,

infections, rehabilitation and restoration of gastrointestinal function.

Secondary outcome

Secondary endpoints include hospital length of stay and microcirculatory

perfusion.

Study description

Background summary

This investigation is based on the hypothesis that perioperative guidance of global tissue perfusion and volemic state by cardiac output and pulse pressure variation is associated with less postoperative complications than arterial blood pressure-guided therapy in patients undergoing abdominal surgery. In the present study we therefore aim to compare these two strategies of perioperative hemodynamic optimization to evaluate the effects of both strategies on patient outcome.

Study objective

Primary objective:
Does perioperative maintenance of cardiac output and pulse pressure variation result in an overall reduction in postoperative complications when compared to

arterial blood pressure-guided perioperative hemodynamics in patients undergoing elective abdominal surgery?

Secondary objectives:
Does perioperative maintenance of cardiac output and pulse pressure variation result in distinct perioperative microcirculatory perfusion patterns when compared to arterial blood pressure-guided perioperative hemodynamics in control patients?
What is the level of agreement between Nexfin and Flotrac arterial blood pressure, cardiac output and PPV.

Study design

Multicenter, single-blinded randomized clinical intervention trial.

Intervention

Intervention: Hemodynamic guidance based on arterial blood pressure or cardiac output with pulse pressure variation.

Study burden and risks

This investigation is associated with a minimal risk for the patient. Most procedures will be performed during general anesthesia and do not divert from routine clinical practice. Only in the 15 minutes before anesthesia induction patients are aware of the finger cuff device and arterial line for arterial blood pressure, cardiac output and pulse pressure variation measurements. Perioperative arterial blood pressure (control A) or cardiac output and pulse pressure variation (CO group)-guided therapy by fluids and/or vasopressors will not divert from standard clinical care. Patients will be phoned at 7 and 30 days after surgery. Thirty days after surgery, patients receive a questionnaire to identify postoperative complications and rehabilitation.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients undergoing elective abdominal surgery
Age 18-85 years
Exptected duration of surgery > 90 minutes
Informed consent

Exclusion criteria

Preexisting cardiac arrhythmias
Emergency operation
ICU patients
Body mass index below 20 kg/m2 and above 40 kg/m2.
Patients without an invasive arterial line
Decompensatio cordis
Aortic valve disease
Ejection fraction < 0.3
Aortic valve stenosis: surface < 1.2 cm2
Pulmonary arterial pressure > 30 mm Hg, TAPSE < 18 mm
Incapacitated patients

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2012
Enrollment:	275
Type:	Actual

Medical products/devices used

Generic name:	Nexfin CC Non-invasive arterial blood pressure monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-09-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-04-2012
Application type:	Amendment
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	NL37830.029.11