MINIMAL INVASIVE MONITORING OF VOLUME STATUS IN PATIENTS AFTER MAJOR ABDOMINAL SURGERY.

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Propofol does not change accuracy of pulse contour cardiac output measurements

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22383

Bron
Nationaal Trial Register

Aandoening

Major abdominal surgery

Ondersteuning

Primaire sponsor: afdeling anesthesiologie van het LUMC
Overige ondersteuning: Institutional funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cardiac output values (thermodilution, LidCO, Vigileo, Hemosonic).

Toelichting onderzoek

Achtergrond van het onderzoek

Determining volume status is important in critically-ill patients. Currently no gold-standard is available to accurately assess a patient's volume status and physicians use clinical signs and hemodynamic parameters (like cardiac output) to estimate volume status.
Currently, the Pulmonary Artery Catheter (PAC) is one of the standards to monitor major abdominal surgery patients. Its use, however, is related to complications upsetting its value in other subpopulations like septic patients. The primary aim of this study is to evaluate the use of less invasive techniques to determine cardiac output (with pulse contour) compared to thermodilution cardiac output measurement with a pulmonary artery catheter. If proven accurate less invasive techniques could replace the PAC in the perioperative monitoring of major abdominal surgery patients.

A second aim of this study is to develop novel techniques to determine mean systemic filling pressure. Mean systemic filling pressure (Pmsf) is the equilibrium pressure in the systemic circulation when there is no flow. Mean systemic filling pressure is thus a measure of volume of the systemic circulation (and thus volume status)[1]. In the operating room and intensive care unit it is not possible to achieve a situation when there is no systemic flow. However, two novel methods can be used to accurately determine Pmsf [2] in heart-beating patients; 1: by arm occlusion or 2: through a ventilator hold maneuver. We hypothesize that a third model can be used; mean systemic filling pressure can be calculated beat-to-beat using cardiac output (CO), stroke volume (SV), central venous pressure (CVP) and mean arterial pressure (MAP) measured during normal ventilation, a single expiratory hold and a single inspiratory hold of 12 seconds. The former two models have been validated in patients after coronary artery by-pass grafting surgery. The two methods to estimate Pmsf have not yet been used in other populations.

Another important issue regarding estimation of volume status is the use of sedative drugs in the ICU and OR and their effects on hemodynamic parameters and their influence on the quality of the measurement of these parameters. In this study we will evaluate the effect of different levels of propofol sedation on Pmsf, venous and arterial resistance and the accuracy of CO measurement with different techniques (for instance pulse contour analysis).

Doel van het onderzoek

Propofol does not change accuracy of pulse contour cardiac output measurements

Onderzoeksopzet

11 min after TCI of propofol has achieved a predicted blood concentration of 6 µg•mL-1, again 11 minutes after the propofol target concentration is lowered to achieve a blood concentration of 4 µg•mL-1 using TCI. These steps are repeated at target propofol concentrations of 2 and 1 µg•mL-1. Subsequently measurements are repeated prior to, 30

seconds after start and 2 minutes after returning to baseline conditions for 30° passive leg raising, PEEP +5 cmH2O and PEEP +10cmH2O. Finally, 500 mL of Voluven is administered in 50 mL bolus with intermediate measurements.

Onderzoeksproduct en/of interventie

Propofol administration at different plasma concentrations.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult patients requiring mechanical ventilation after elective esophagus resection or Whipple surgery admitted to the post-anaesthesia care unit (PACU) with an indication for pulmonary artery catheter monitoring.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Hemodynamic instability with a mean arterial pressure (MAP) < 70 mm Hg, central venous

pressure (CVP) >18 mm Hg and/ or a cardiac index < 2.0 L•min-1 or dependence on high dosages of inotropic drugs after admittance to the PACU;

2. Severe arrhythmias;

3. Intra-cardiac shunts;

4. Prior diagnosis of aberrant cardiovascular anatomy;

5. Symptomatic peripheral vascular disease;

6. Symptomatic pulmonary disease;

7. Clinically significant aortic aneurysm;

8. Significant valvular regurgitation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2010
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-08-2010

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2379
NTR-old	NTR2486
Ander register	EudraCT / CME / WEC : 2010-019073-15 / P10.67 / 0908;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A