Prospective combined validation of an algorithmic calculated mean systemic filling pressure with transpulmonary pressure measurements during thoracic drainage and 3D TOE measured hemodynamic parameters.

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1. Is PmsALG comparable with PmsINSP, even with changing Ppl?2. Is PmsARM comparable with PmsINSP and PmsALG?3. Does thoracic drainage have influence on pleural pressures measured by esophageal balloon catheter to determine transpulmonary pressure?4...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON47962

Source
ToetsingOnline

Brief title
Validation of Pms, transpulmonary pressure in drainage and 3D TOE.

Condition

- Heart failures

Synonym
Circulatory failure

Research involving

Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Wetenschapsfonds Intensive Care Catharina Ziekenhuis

Intervention

Keyword: 3D TOE, Mean systemic filling pressure, Thoracic drainage, Transpulmonary pressure

Outcome measures

Primary outcome

Endpoint 1:

1. PmsARM and PmsINSP give a reliable reflection of volume state.

2. A linear trend or correlation can be observed when comparing PmsALG with

PmsARM and PmsINSP.

Secondary outcome

Endpoint 2:

1. The pressure difference of Pes differs <5cm H2O compared to the peripheral

pleural pressure measured

2. The pressure difference of Per changes linear with the change in pleural

pressure during different negative drainage pressures.

Endpoint 3:

1. Cardiac parameters measured with perioperative 3D TOE change <10% in

comparison to PiCCO and carotid artery measurement.

Study description

Background summary

Volume-state in critically ill patients is a difficult parameter to determine, and knowledge about it could make the difference between life or death concerning proper treatment. Determination of volume state starts with adequate 3D transesophageal echocardiography (TOE) in the operation room, including with non-invasive doppler carotid artery measures. TOE is a standardly used method in cardiac surgery. Because echocardiography only gives information about volume status at a certain timepoint, a real-time continuous value reflecting volume-status is needed. "Mean systemic filling pressure (Pms)" appears to be a promising value reflecting volume status. There are clinically and patient-unfriendly methods available which to date serve as a gold standard to determine Pms. However, these methods cannot be used in daily practice because of the aforementioned reasons. Therefore there is a need for a non-invasive methods measuring Pms, which could now be determined by an algorithm (PmsALG). It is key to compare this PmsALG with its gold standards (inspiratory breath hold; PmsINSP) and a more minimally invasive but certainly not patient-friendly determination of Pms by blood pressure cuff measurement in an arm (PmsARM) in order to establish a clinical validation for PmsALG.
While validating PmsALG, one has to consider the intrathoracic pressure by performing esophageal pressure measurements (Ppl) using a esophageal balloon to be able to calculate which pressure changes are exactly attributable to the Pms measurement during an inspiratory breath hold. Coincidentally this gives opportunity to determine what the clinical value of oesophageal pressure measurements is during thoracic drainage in post cardiac surgery patients, for this has never been investigated. By combining all these entities, the investigators hope to be able to give a better estimation of intravascular fluid status in order to prevent hyper/hypovolemia and eventually create a better outcome for ICU-patients.

Study objective

1. Is PmsALG comparable with PmsINSP, even with changing Ppl?
2. Is PmsARM comparable with PmsINSP and PmsALG?
3. Does thoracic drainage have influence on pleural pressures measured by esophageal balloon catheter to determine transpulmonary pressure?
4. What is the difference between cardiac parameters and non-invasive perioperative values determined by 3D transoesophageal echocardiography (TEE) compared with PiCCO and carotid echo doppler?

Study design

Prospective observational cohort analysis.

Study burden and risks

Minimal burden for the patient, as all study procedures will take place under full sedation.

Inspiratory breath hold:
Standard method without risks.

Esophageal balloon catheter:
No hazard, small risk of bleeding (in theory) which has never occurred in practice.

PiCCO catheter:
Standard Intensive Care equipment. Small risk of bleeding or catheter-related infection (in theory) which has never occurred in practice.

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

- 18yrs or older
- SIgned informed consent
- Elective coronary artery bypass surgery
- Postoperative mechnically ventilated admitted to the PACU

Exclusion criteria

- Withdrawal informed consent
- History of pneumonectomy of lobectomy
- Mechnical support of circulation
- COPD Gold 3 or 4
- Contra-indications for esophageal balloon: esophageal tumors, ulcerations, diverticulitis, varices bleeding, recent esophageal surgery, sinusitis, epistaxis, recent nasopharyngeal surgery.
- Complications during surgery
- Postoperative bleeding >50mL/15 minutes after admission to PACU
- No thoracic drain in pleura
- Postoperative pneumothorax
- Participation in other research studies/trials
- Elevated intra-abdominal surgery (>12 mmHg)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-06-2019

Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Oesophageal balloon catheter / PiCCO catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-03-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-06-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL67389.100.18