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Do positive end-expiratory pressure-induced changes in cardiac output indicate fluid responsiveness in anaesthetised patients?

Submission date 04/01/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/02/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/02/2007	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
The magnitude of changes in cardiac output induced by alternating Positive End-Expiratory Pressures (PEEP) predict fluid responsiveness in anaesthetised patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by The Scientific Ethical Committee of North Denmark Region on 13th December 2006.

Study design
Interventional, single centre, non-randomised or blinded trial

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Anaesthetised patients

Interventions
While monitoring cardiac Stroke Volume (SV) we alternate the Positive End-Expiratory Pressure (PEEP) by 10 cm H2O. If the PEEP-alteration results in a change in SV of more than 5 mL we hypothesise that the patient is fluid responsive.

Subsequently we measure SV before and after loading the patient with 250 mL of Hydroxyethyl Starch (Voluven®) to obtain a measure of the patients fluid responsiveness.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Hydroxyethyl Starch (Voluven®)

Primary outcome measure
Coherence between the magnitude of the PEEP-induced alterations of SV and the patients fluid responsiveness.

Secondary outcome measures
1. Coherence between the magnitude of PEEP-induced alterations of pulse pressure and the patients fluid responsiveness
2. Coherence between the magnitude of PEEP-induced alterations of heart rate and the patients fluid responsiveness

Overall study start date
08/01/2007

Completion date
01/09/2007

Eligibility

Key inclusion criteria
Patients admitted to Aalborg Hospital for elective surgery of the spinal column.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Severe right-sided cardiac insufficiency
2. Severe anaemia
3. Pregnancy
4. Children (age less than 18 years)
5. Patients without esophageal doppler monitoring of cardiac output
6. Patients who experience severe complications during anaesthesia

Date of first enrolment
08/01/2007

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
Denmark

Study participating centre
Anaesthesia and Intensive Care Medicine of North Denmark Region
Aalborg
Denmark
9000

Sponsor information

Organisation
Anaesthesia and Intensive Care Medicine of North Denmark Region (Denmark)

Sponsor details
Soendre Skovvej 3, 2.
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ndn@rn.dk

Sponsor type
Hospital/treatment centre

Website
http://www.an.rn.dk

ROR
https://ror.org/003gkfx86

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Anaesthesia and Intensive Care Medicine of North Denmark Region (Denmark)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration