

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/02/2007	Condition category Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 (Volumen®) 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.

Aalborg

Denmark

9000

+45 993 28057

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