Does standard opening of the lungs after intubation improve lung and heart function?

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28816

Source
NTR

Brief title
EARLY OPEN

Health condition

Lung recruitment
Atelectasis
Right ventricle
Electrical Impedance Tomography
Echocardiography

Sponsors and support

Primary sponsor: No sponsers
Performed by Academic Medical Centre
Source(s) of monetary or material Support: No funding

Intervention

Outcome measures

Primary outcome

Regional lung aeration assessed by Electrical Impedance Tomography

Secondary outcome

Right ventricular function (contractile –, preload – and afterload–parameters) and overall cardiac function assessed by trans thoracic echocardiography

Study description

Background summary

Invasive mechanical ventilation requires tracheal intubation. Intubation is facilitated by muscle paralysis, which could induce further atelectases. Atelectases compromise gas–exchange and depresses cardiac function. Early recruitment maneuvers (RMs) could resolve atelectases, but it is uncertain whether they should be applied in every intubated intensive care patient (i.e., early after intubation) or only in whom gas–exchange does not improve (i.e., only when necessary).
Therefore a strategy using early recruitment maneuvers (RMs) after intubation is compared with a strategy using RMs only on indication in intensive care patients. We hypothesize that early RMs homogenize and improve lung aeration and subsequently improves right ventricular function.

Study objective

Early recruitment maneuvers (RMs) after intubation result in a reduction of atelectases and subsequently improved cardiac function in comparison with standard care

Study design

t0: Within 30 minutes after intubation but just before lung recruitment

t1: 1 hour after lung recruitment

t2: 24 hours after lung recruitment

Intervention

Lung recruitment maneuvers after intubation: increasing driving pressure with steps of 10 cm H2O with an inspiratory hold of 10 seconds after each step. At a maximum of 40 cm H2O of

driving pressure, PEEP is increased form 5cm H2O to 10cm H2O and the driving pressure decreased in steps of 10 cm H2O to 6-8ml tidal volume /kg lean body weight.
The standard care group will receive after intubation a similar driving pressure to obtain 6-8ml tidal volume /kg lean body weight, but with 5 PEEP and without lung recruitment (only on indication if hypoxia is present at the discretion of the attending physician

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Eligibility criteria

Inclusion criteria

Intubation to be performed after which
trans thoracic echocardiogram and

Electrical Impedance Tomography is feasible

Exclusion criteria

Refractory circulatory instability
Poor LV function (Ejection fraction < 30%) or signs of obliteration
Intracranial hypertension
Undrained pneumothorax or severe bullae
Presence of a pacemaker, chest drains or implantable pumps

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-09-2013
Enrollment:	34
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-09-2013
Application type:	First submission

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
NTR-new	NL4002
NTR-old	NTR4174
Other	Cherpanath : Thomas
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A