External Strips during Recruitment Maneuver to Improve FRC in patients with ALI

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This study is aimed to compare the changes of FRC after performance of three different placements of external stripes during recruitment maneuver

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON38376

Source
ToetsingOnline

Brief title
External Strips during Recruitment maneuver

Condition

- Respiratory tract infections

Synonym
ALI, recruitment maneuver

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Airway Pressure, External Strips, FRC, Recruitment Maneuver

Outcome measures

Primary outcome

The effect of external stripes with standardized recruitment maneuver on FRC.

Secondary outcome

Blood pressure

Study description

Background summary

Healthy lung needs a low pressure to open up collapsed alveoli, whereas diseased lung needs higher pressure due to a lack of surfactant. Open up these collapsed alveoli is aimed to improve the functional residual capacity (FRC), and therefore improve lung oxygenation. We have shown that recruitment maneuver with high pressure up to 70-80 cmH2O is needed to open up atelectasis in diseased lungs but the use of this pressure may increase the risk of barotrauma and/or hemodynamic instability. Therefore we would like to study if we could open up diseased lung with lower pressure up to 60 cmH2O by reducing thorax compliance with the placement of external stripes. We have seen in clinical practice that putting CVVH fluid sacs (4-5 kg) on the sternum leads to better recruitment of collapsed alveoli with improvement of FRC and oxygenation by reducing right-left shunt over the lung. Therefore we expect that the placement of external stripes around the thorax will mimic these sacs and the effect of a recruitment maneuver with a pressure of 60 cmH2O on FRC is better compared to recruitment without external stripes.

Study objective

This study is aimed to compare the changes of FRC after performance of three different placements of external stripes during recruitment maneuver

Study design

Intervention study in ALI patients.

Intervention

This study is aimed to compare the changes of FRC by recruitment maneuvers with and without external stripes.

Study burden and risks

In this study, we will use a standardized recruitment maneuver with a maximal pressure of 60 cmH2O w6 that has proven to be safe in earlier studies and is nowadays used as standard care in the ventilatory management of patients with ALI (beademingsprotocol ICV intranet Erasmus MC).

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

- ALI according to American-European consensus criteria
- Mechanically ventilated on the second or the third day
- Aged >18 years old
- Supine position
- Written informed consent from legal representatives

Exclusion criteria

- ARDS
- Bullae and/or pneumothorax
- Patient with high intracranial pressure
- Critically ill patients with pH <7.2 or with cardiovascular instability which is defined as hypotension (systolic blood pressure (SBP) <90 mmHg, or mean arterial pressure <60 mmHg) or normotension in combination with a dose of NOR at an infusion rate of more than 0.5 µg/kg/min.
- Multi trauma with spinal, thoracic or abdominal trauma
- Large breast
- Morbid obese

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2012
Enrollment:	16
Type:	Anticipated

Medical products/devices used

Generic name:	External Stripes
Registration:	No

Ethics review

Approved WMO Date:	10-07-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL35545.000.11