Routine manual hyperinflation versus on demand manual hyperinflation in intubated and mechanically ventilated post*cardiothoracic surgery patients * A randomized controlled trial *

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To compare a *routine* MH strategy with an *on demand* MH strategy in cardiothoracic surgery patients with respect to post*extubation SpO2 and FRC.

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

Summary

ID

NL-OMON32559

Source ToetsingOnline

Brief title Routine Manual Hyperinflation vs On Demand Manual Hyperinflation

Condition

• Respiratory tract infections

Synonym Bagging, manual ventilation

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: airway management, mechanical ventilation

Outcome measures

Primary outcome

peripheral hemoglobin oxygen saturation (SPO2)

Functional Residual Capacity (FRC)

Secondary outcome

The number of MH maneuvers per patient (routinely performed as well as those on

indication in the *routine* strategy group versus *on demand* in the *on

demand* strategy group)

Duration of tracheal intubation

Length of stay in the intensive care unit

Study description

Background summary

Manual hyperinflation (MH) is a frequently performed maneuver as part of airway management in intubated and mechanically ventilated patients. MH involves disconnecting the patient from the mechanical ventilator and inflating the lungs via a manual resuscitation bag.

In case of noted sputum in the airways or when peripheral hemoglobin oxygen saturation (SpO2) falls, MH is often a first step to improve mechanical ventilation and oxygenation (so*called *on demand* MH). Some experts advocate performing MH more frequently, on a routine basis (so*called *routine* MH, e.g., every 6 hours).

Although mobilization of airway secretions, prevention of sputum plugging and improved alveolar recruitment are cited as potential benefits of MH there is no solid evidence supporting this, above all not for *routine* MH. Of note, MH could be associated with adverse events and also could cause agitation of the patient .

Functional residual capacity (FRC) after cardiothoracic surgery is reduced significantly. Since MH could improve alveolar recruitment and as result the FRC, *routine* MH may benefit these patients.

Study objective

To compare a *routine* MH strategy with an *on demand* MH strategy in cardiothoracic surgery patients with respect to post*extubation SpO2 and FRC.

Study design

Randomized clinical trial

Two MH strategies are compared: For the first strategy in 50 patients MH is performed routinely for the second strategy in 50 patients the MH procedure is performed only on indication.

Intervention

not applicabel

Study burden and risks

MH is part of the daily care of mechanical ventilated patients. For this study at four different times FRC is measured.

FRC-measurement is a non-invasive procedure; it will take about 10 minutes of the patient*s time and is well tolerated.

At the same moment SPO2 is measured with pulse oximetry, which is also a non-invasive procedure which is not burdensome to the patient. No additional bloodsamples are taken.

Contacts

Public Academisch Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Patients planned for coronary artery bypass grafting and/or valve surgery are recruited > 18 years of age written informed consent

Exclusion criteria

(Previous) pulmonary surgery Pulmonary infection

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

4 - Routine manual hyperinflation versus on demand manual hyperinflation in intubate ... 24-05-2025

Primary purpose:

Prevention

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	15-09-2008
Enrollment:	100
Туре:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
Other	kandidaat registratie NTR 3640
ССМО	NL24317.018.08