Effect of high-frequency chest wall oscillation and manual hyperinflation on the resolution of atelectasis in ventilated patients

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Studies provide statistically significant evidence of the effectiveness of high-frequency chest wall oscillation administered via The Vest* System.St. Elisabeth Ziekenhuis Tilburg wants to demonstrate the effectiveness of HFCWO on ventilator-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON30499

Source
ToetsingOnline

Brief title
Oscillation or manual hyperinflation

Condition

- Bronchial disorders (excl neoplasms)

Synonym
atelectasis, mucusplug

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis

Source(s) of monetary or material Support: Hill-Rom,Is niet van toepassing. Het onderzoek heeft financieel geen gevolgen

Intervention

Keyword: atelectasis, manual hyperinflation, oscillation, The Vest airway clearance system

Outcome measures

Primary outcome

Primary study parameters are:

*age

*sex

*primary diagnosis

*APACHE-score

*Ventilator-mode

*FiO2

*Inspir./ expir. relation

*mandatory breaths

*Expired minute volume and tidal volume

*Peak airway pressure

*positive end-expiratiore pressure

*SaO2

*PeCO2

*Dynamic compliance

*Mean art. pressure (MAP)

*Hartrate

*bodytemperature

*suction frequency

*x-ray diagnosis

*bronchoscopic suction

*transfer to an other unit

*Leukocyte count

* use of antibiotics

Measuringmoments:

o T-0 = 1th measuringmoment, immediately before start intervention

o T-1 = 2th measuringmoment, immediately after finish intervention

o T-2 = 3th measuringmoment, 1 hour after intervention

Secondary outcome

not applicable

Study description

Background summary

Critically ill patients who needs to be ventilated are unable te move spontaneously.
The are nursed in the supine position for extended periods of time.
Immobilisation may occur significant effects in the respiratory system.
Rechearch demonstrate that an effect of prolonged immobilization is atelectasis, accumulation of mucus.
Atelectasis results in development of a shunt with attendant hypoxemia.
The pooled and stagnant secretions may act as a nidus for bacterial proliferation, culminating in nosocomial pneumonia.
Treatment of atelectasis involves positive end-expiratory pressure, postural drainage and manual hyperinsuflation.
In patients with nonresolving atelectasis, bronchoscopic suctioning may be resorted to.
Bronchoscopy is an invasive and expensive procedure.

Patients with cystic fibrosis also risks to develop atelectasis.
Studies provide statistically significant evidence of the effectiveness of high-frequency chest wall oscillation (HFCWO)administered via The Vest* System.

Study objective

Studies provide statistically significant evidence of the effectiveness of high-frequency chest wall oscillation administered via The Vest* System.
St. Elisabeth Ziekenhuis Tilburg wants to demonstrate the effectiveness of HFCWO on ventilator-dependent patients.
Objective:
Effect of high-frequency chest wall oscillation and manual hyperinflation on the resolution of atelectasis in ventilated patients.

Study design

A prospective, randomized, experimentally, single center study.

Intervention

Patients who meets the entry criteria and agree to participate in the study will be split up by randomisation.
10 Patients will be the intervention group and treaded with The Vest* therapy and 10 patients treated with postural drainage and manual hyperinflation.
The intervention group will receive an inflatable vest connected by two tubes to a small air-pulse generator.
The air-pulse generator rapidly inflates and deflates the vest, gently compressing and releasing the chest wall up to 20 times per second during 20 minutes, 3 times a day.
This process creates mini-coughs that is dislogde mucus from the bronchial walls, increase mobilization, and move it along toward central airways.Once the mucus has moved from the smaller to larger airways, it can be easily removed by suctioning.
Both treatments will end when the atelectasis are not visible any more on the chest radiograph or maximally 3 days.
In patients with nonresolving atelectasis after 3 days of treatment, bronchoscopic suctioning will be resorted to.

Study burden and risks

The Vest* System may have a negative influence on the ventilation or hemodynamics.
The Vest* System is widely accepted and prescribed to treat secretion-related pulmonary complications in more than 470 diseases and conditions, including muscular dystrophy, spinal cord injury, chronic obstructive pulmonary disease (COPD), multiple sclerosis (MS), cerebral palsy (CP) and cystic fibrosis (CF).

The Vest* System is also being used to maintain healthy lung function in post-operative, ICU and post-lungtransplantation patients.
Atelectasis is difficult to manage and can lead to severe pulmonary complications.
The Vest* System demonstrate the efficacy and safety for a variety of patients with high risks of secretion-related pulmonary complications such as atelectasis without annoying side effects.
Maybe it also demonstrate his efficacy and safety for ventilator-dependent patients with atelectasis.
Ventilator-dependent patients are monitored constantly and every minimum change in state of health will be noticed and responded adequately.

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

patients older than 18 years
Atelectasis visible radiographically
Informed consent

Exclusion criteria

Patients with coagulationproblems
Patients with cancer and metastasis in the thorax area
Patients with spinal column fracture
Patients with spinal cord injury
Patients with recent rib fracture
Patients with high intracerebal pressure
Patients who are bleeding
Patients with open wounds at the thoracal area
Patients with thoraxtubes
Restless patients

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2007
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	The Vest airway clearance system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-01-2007
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL15572.008.06