Effectiveness of routine nebulisation of mucolytic agents and bronchodilating drugs in intubated and ventilated intensive care unit patients.

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To determine the efficiency, safety and health care costs of a strategy using routine nebulisation of mucolytics and bronchodilators four times daily, with a strategy of nebulisation on a strict clinical indication only, in mechanical ventilated...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON41284

Source
ToetsingOnline

Brief title
Nebulae

Condition

- Bacterial infectious disorders
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
lung failure, Respiratory insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Bronchodilator (salbutamol), Mechanical ventilation, Mucolytic (acetylcysteine), Nebulisation

Outcome measures

Primary outcome

The primary clinical endpoint is the number of ventilator-free days, defined as the number of days from day 1 to day 28 after ICU admission and start of ventilation, on which a patient breathes without assistance of the ventilator, if the period of unassisted breathing lasted at least 24 consecutive hours. Patients who die or are mechanically ventilated longer than this period are assigned zero ventilator-free days.

Secondary outcome

Secondary clinical endpoints are: (a) ICU lenght of stay (b) hospital length of stay (c) ICU mortality (d) hospital mortality, (e) incidence of secondary ARDS using consensus criteria (d) ventilator-associated pneumonia (e) atelectases (f) any side effect of nebulisation of mucolytics and bronchodilatators or the nebulisation itself

In addition, related health care costs will be estimated from a health system perspective including costs of (a) ventilation and (b) stay in ICU and/or hospital; (c) costs of cumulative use of sedatives and neuromuscular blocking agents, (f) the use of tracheostomies (g)

ventilator-associated pneumonia.

Study description

Background summary

Nebulisation of mucolytics and bronchodilators is a frequently applied routine strategy in intubated and mechanically ventilated intensive care unit (ICU) patients. With the aim of preventing sputum plugging and atelectasis by diluting pulmonary secretion in sedated paralyzed patients, who are less able to clear their airways trough coughing. Benefits are unknown and since very little to no sedation or muscle paralysis is provided during mechanical ventilation nowadays, questions rise whether this this time- and money-consuming strategy could be considered obsolete. In addition, side effects of the nebulisation can occure. There are no randomized controlled trials looking at the clinical efficiency and economical consequences of preventive nebulisation of mucolytica and bronchodilators in ventilated patients.

Study objective

To determine the efficiency, safety and health care costs of a strategy using routine nebulisation of mucolytics and bronchodilators four times daily, with a strategy of nebulisation on a strict clinical indication only, in mechanical ventilated intensive care patients.

Study design

An investigator-intitiated multicenter randomised controlled non-inferiority trial in intubated and ventilated ICU patients. In seven participating centers 950 patients will be randomised between
1. four times daily routine nebulisation of mucolytics and bronchodilators
2.nebulisation of mucolytics and/or bronchodilators on clinical indication

Intervention

1. four times daily routine nebulisation of mucolytics and bronchodilators
2 nebulisation of mucolytics and/or nebulisation on clinical indication.

Study burden and risks

Risks of routine nebulisation are unknown in mechanical ventilated patients. Nebulisation of mucolytics is suggested to prevent and/or delay endotracheal

tube occlusion and sputum plugging, by dilute sputum, although no solid research is available. Nebulisation with acetylcysteine may lead to bronchospasm and with salbutamol may be associated with tachycardia, tachyarrhythmia, tremor, agitation.

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

Age 18 year or older
Eexpected duration of intubation and ventilation > 24 hour
Written informed consent

Exclusion criteria

Ventilation before present ICU admission (though short-term ventilation in the emergency room or in the operation room for general anesthesia during surgery is allowed)
Pregnancy
Lung disease for which inhalation therapy and/or oral steroids are used
Diagnoses of: Guillain-Barré syndrome, complete spinal cord lesion or amyotrophic lateral sclerosis, multiple sclerosis and myasthenia gravis
Allergy for acetylcysteine or salbutamol

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2014
Enrollment:	950
Type:	Actual

Ethics review

Approved WMO Date:	06-05-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-05-2014
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-05-2016
Application type:	Amendment
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
CCMO	NL47807.018.14
Other	NTR4465, NTC02159196