

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bacterial infectious disorders
<b>Study type</b>	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 length 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 bronchodilators 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 through coughing. Benefits are unknown and since very little to no sedation or muscle paralysis is provided during mechanical ventilation nowadays, questions rise whether this time- and money-consuming strategy could be considered obsolete. In addition, side effects of the nebulisation can occur. There are no randomized controlled trials looking at the clinical efficiency and economical consequences of preventive nebulisation of mucolytics 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-initiated 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

### Public

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### Scientific

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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  
Expected 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