Effect of daily nebulisation of a mucolytic and bronchodilation agent in intensive care patients in need for mechanical ventilation because of lungfailure

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24245

Source
NTR

Brief title
Nebulae

Health condition

Lung failure
Nebulisation
Mechanical ventilation
Bronchodilator (salbutamol)
Mucolytic (acetylcysteine)

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Number of ventilator-free days (VFDs), defined as the number of days from day 1 to day 28 after ICU admission and start of mechanical ventilation

Secondary outcome

-ICU and hospital length of stay
-ICU and hospital mortality
-secondary ARDS
-ventilator-associated pneumonia
-atelectasis
-side effects of nebulisation of mucolytics and bronchodilators
-related health care costs will be estimated with a cost benefit – and budget impact analysis

Study description

Background summary

Objective: determine the effect of a strategy using routine nebulisation of mucolytics and bronchodilators (four times daily) as compared to a strategy using nebulisation of mucolytics or bronchodilators only on clinical indication (i.e. occurrence of persistent thick and tenacious sputum or bronchospasm) in mechanically ventilated intensive care patients. Design: investigator initiated multicenter randomized controlled non-inferiority trial in mechanically ventilated intensive care patients. Main endpoints: number of ventilator-free days (VFDs), ICU and hospital length of stay and mortality, incidence of secondary ARDS, ventilator-associated pneumonia, atelectasis and side effects of nebulisation of mucolytics and bronchodilators. Also, related health care costs will be estimated with a cost benefit – and budget impact analysis.

Study objective

A strategy restricting nebulisation of mucolytics and bronchodilators to patients with sputum plugging is as effective as, but cheaper and safer than, a strategy using routine nebulisation in all intubated and mechanically ventilated ICU patients.

Study design

From admission at the ICU and start of ventilation till discharge of the ICU, 90 days follow up telephone call

Intervention

Routine nebulisation of mucolytics and bronchodilators administered every 6 hours is compared to nebulisation of mucolytics and bronchodilators on strict clinical indication (i.e., only if a patient shows to have problems with sputum clearance or bronchospasm).

Contacts

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Eligibility criteria

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)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2014
Enrollment:	950
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-03-2014
Application type:	First submission

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
NTR-new	NL4312
NTR-old	NTR4465
Other	NL4780701814 :

Study results