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

Gepubliceerd: 17-03-2014 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24245

Bron
NTR

Verkorte titel
Nebulae

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

Department of Intensive Care
Academic Medical Center, University of Amsterdam
Meibergdreef 9, G3-228
Sophia Hoeven, van der
Amsterdam 1105 AZ
The Netherlands
+31-20-5666345

Wetenschappelijk

Department of Intensive Care
Academic Medical Center, University of Amsterdam
Meibergdreef 9, G3-228
Sophia Hoeven, van der
Amsterdam 1105 AZ
The Netherlands
+31-20-5666345

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2014
Aantal proefpersonen:	950
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-03-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4312
NTR-old	NTR4465
Ander register	NL4780701814 :

Resultaten