Physiological effect High-flow Tracheal Oxygen on Viscosity of Airway Mucus and Respiratory Effort ain Patients Weaning from Invasive Mechanical Ventilation

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Primary Objective: To determine the difference in change in sputum viscoelasticity on HME and HFTO during disconnection sessions from the ventilator in tracheotomised patients. Secondary Objective(s): 1. To determine the difference in respiratory…

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON57061

Source
ToetsingOnline

Brief title
PIONEER

Condition

- Respiratory disorders NEC

Synonym
respiratory failure, weaning from mechanical ventilation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Fisher & Paykel Healthcare

Intervention

Keyword: heat-moisture exchanger, high-flow tracheal oxygen, mechanical ventilation, weaning

Outcome measures

Primary outcome

The primary end-point is the difference between HME and HFTO in change in sputum viscoelasticity from baseline to the end of the long disconnection sessions (>=12 hours). Viscoelastic (G*) is made up of elasticity (G*) and viscosity (G**) of mucus at a 5% strain rate (or linear viscoelastic region, which reflects the small deformation regime) and the critical stress (* critical)· and strain (y critical) of mucus, which reflect the behavior of mucus under high amounts of shear stress and thus the large deformation regime.

Secondary outcome

1. The difference between HME and HFTO in change in sputum viscoelasticity from baseline to the end (after 10-90 min) of the early disconnection session

2. The difference in respiratory effort between HME and HFTO during early disconnection sessions measured by median PES-swing during the early disconnection session.

3. The difference in frequency of presence of self-reported dyspnea sensation and discomfort between HME and HFTO during early and late disconnection sessions. Presence of self-reported dyspnea and discomfort is evaluated by asking patients as described in section 8.3.

4. The difference in severity of self-reported dyspnea sensation and

experienced discomfort between HME and HFTO during early and late

disconnection. Severity of self-reported dyspnea and discomfort is evaluated

using a dyspnea visual-analog scale (D-VAS) as described in section 8.3.

Study description

Background summary

A majority of critically ill patients treated in the intensive care unit (ICU) require invasive mechanical ventilation (iMV). Although iMV is an essential part of treatment, its duration is directly linked to clinical outcomes. Long-term iMV is expensive and requires a lot of intensive care resources. That is why the early and safest possible release of iMV is one of the most important goals and challenges in ICU care. Liberation is usually preceded by a period of weaning off ventilation, which is often done with a tracheostomy in patients with long-term iMV. Advantages of weaning with tracheostomy compared to an endotracheal tube include a decreased need for sedatives, the ability to eat and speak, and possibly a lower mortality rate.

Despite the significant burden on patients and ICU resources, insights into the weaning phase with tracheostomy are limited. Patients with a tracheostomy are at risk of dehydration of the airway mucosa and sputum accumulation during weaning from mechanical ventilation. High-flow tracheal oxygen (HFTO) and heat-moisture exchanger (HME) are used as adjunctive therapy during uncoupling sessions in tracheostomy patients weaning from invasive mechanical ventilation (IMV) to limit dryness while maintaining oxygenation. We recently summarized the studies comparing the physiological effects of both interfaces in a systematic review and identified areas where knowledge is lacking: the effect on sputum viscoelasticity, respiratory effort early in the withdrawal process and the sensation of shortness of breath . We hypothesize that HFTO, compared to HME, reduces sputum viscoelasticity and provides respiratory support during withdrawal. This may improve weaning by facilitating the clearance of mucus from the airways, preventing respiratory failure, and providing comfort by reducing shortness of breath.

Study objective

Primary Objective:
To determine the difference in change in sputum viscoelasticity on HME and HFTO during disconnection sessions from the ventilator in tracheotomised patients.

Secondary Objective(s):
1. To determine the difference in respiratory effort between disconnection sessions with HME and HFTO, as measured by swings in esophageal pressure (PES)
2. To determine the difference in presence and severity of self-reported dyspnoea sensation and discomfort between disconnection sessions with HME and HFTO.

Study design

Pilot physiological study with a randomized cross-over design

Intervention

Upon signing informed consent, patients will be randomized (1:1) in one of the 2 study arms, in order to eliminate any subjective clinical judgement whether a patient is likely to benefit from HFTO and to control for confounding factors. The study arms are start HME and cross over to HFTO, or start HFTO and cross over to HME. The same order is used during measurements during disconnection sessions early and late in the weaning phase. Randomization will be performed through a web-based system (Castor) using computer-generated random numbers with blocks of 2 and 4, unknown to the investigators. Blinding does not apply as the intervention is not possible to blind.

Study burden and risks

The study compares two therapeutic modalities both used in clinical care without side-effects or complications. Study procedures and measurements consist of standard clinical procedures that are performed daily in clinical setting with negligible risk of deterioration for the patient. During weaning with HFTO sputum clearance might be more easy for the patient and respiratory effort might decrease, both are assumed to be beneficial for the weaning process of the patient.

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 years
• Scheduled to wean from mechanical ventilation with tracheostomy

Exclusion criteria

• Longstanding tracheostomy, defined as tracheostomy being present prior to current hospital admission
• Tracheostomy primarily indicated for chronic upper airway obstruction or to secure airway patency due to persistent stupor/coma
• Chronic positive pressure respiratory support at home (excluding night-time continuous positive airway pressure for sleep apnea)
• Mucociliary disease in medical history (e.g. cystic fibrosis, pulmonary ciliary dyskinesia)
• Neuromuscular disease in medical history (excluding ICU-acquired weakness)
• Contra-indication placement oesophageal balloon for measurement of PES:
o Fractures in mandibular, orbital or ethmoid bone or skull base
o Esophageal varices or surgery in medical history
o Severe bleeding disorders
• Hemoptysis in 72 hours prior to the first disconnection session. Clinically relevant hemoptysis is defined as hemoptysis requiring tracheal/endobronchial or radiologic intervention, or administration of pro-coagulating drugs such as tranexamic acid.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	29-10-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL87502.078.24