Mechanical insufflation-exsufflation (Cough Assist) in Critically Ill Adults: A randomized controlled trial

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52221

Source
ToetsingOnline

Brief title
ACACIA-trial

Condition

- Other condition
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
respiratory secretion accumulation

Health condition

airway clearance - mucociliary clearance

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,NWO docentenbeurs nr: 023.011.016 t.n.v. W. Stilma

Intervention

Keyword: Intensive Care, invasively ventilated patients, mechanical in-exsufflation

Outcome measures

Primary outcome

The primary outcome is the proportion of delivered MI-E sessions (2 times a MI-E session of 3 cycles per calendar day) per patient according to study protocol (feasibility).

Secondary outcome

Secondary outcomes are the total number of serious adverse events (incidence of pneumothorax and serious hemodynamic of pulmonary instability) in relation to MI-E (safety) and preliminary exploratory data on clinical outcomes including duration of invasive ventilation, length of stay in ICU and mortality (efficacy).

Study description

Background summary

In invasively ventilated critically ill patients, removal of airway secretions is typically performed by mimicking a cough followed by endotracheal suctioning. A cough can be mimicked by applying manual hyperinflation, which is an uncontrolled maneuver with high risks. Another way to mimic a cough is by means of mechanical insufflation exsufflation (MI-E), which is more controlled, and by that probably safer and more effecious than manual hyperinflation. Also, MI-E could be more comfortable for the patient. It is uncertain, however, whether MI-E is feasible, safe, and effective in invasively ventilated

critically ill patients.

Study objective

The primary objective of this study is to evaluate the feasibility of MI-E in invasively ventilated critically ill patients.
The secondary objective is to evaluate safety and explore data on the efficacy of MI-E in invasively ventilated critically ill patients with regard to need for airway care interventions, duration of invasive ventilation and mortality.

Study design

Multicentre randomized clinical feasibility trial.

Intervention

Bedside nurses, trained in using the MI-E device, will apply MI-E sessions at two moments per calendar day (morning and afternoon) for a maximum of 7 days while a patient is invasively ventilated. Airway secretions are removed by endotracheal suctioning, as part of routine airway care. Manual hyperinflation will only be used when necessary in an emergency situation.

Study burden and risks

The technique currently used to mimic a cough for invasively ventilated critically ill patients is manual hyperinflation. Manual hyperinflation could be accompanied or replaced by MI-E as part of regular airway care. MI-E could bring risks associated with the procedure due to disconnection from the ventilator and the settings of MI-E. MI-E could be associated with possible benefits due to a more controlled way to mimic a cough while insufflated and exsufflated pressures are applied according to the defined settings. Additionally the need for deeper tracheal suctioning may be reduced.

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

• admission to one of the participating ICUs; and
• intubated with an endotracheal tube; and
• expected to need invasive ventilation for more than 48 hours from consideration for inclusion.

Exclusion criteria

age <18 years;
already use of MI-E before hospital admission, i.e., at home; known presence of bullous emphysema; known bronchopleural fistula; known pneumothorax or pneumomediastinum; known rib fractures or unstable spinal fractures; unsecured subarachnoidal haemorrhage; uncontrollable intracranial pressures. Patients in aerogenic isolation, apart from cohort isolation due to COVID-19, are also excluded.

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	08-05-2024
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	mechanical insufflation-exsufflation
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-11-2022
Application type:	First submission
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	NL76195.018.22