Effect of an Automated Secretion Removal Technology, named TrachFlush, on the Need for Tracheal Suctioning * a study in intubated and mechanically ventilated intensive care unit patients

Published: 09-07-2021
Last updated: 08-04-2024

The primary objective of this study is to evaluate whether use of the TrachFlush reduces the need for tracheal suctioning. In a selection of patients, one secondary objective is to ascertain the exact volume of airway secretions that is pushed past...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

Summary

ID

NL-OMON51050

Source
ToetsingOnline

Brief title
TrachFlush

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
respiratory secretion accumulation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,AW TECHNOLOGIES ApS, Nørresundby, Denmark

Intervention

Keyword: critical care, invasive ventilation, secretion clearance, tracheal suctioning

Outcome measures

Primary outcome

The proportion of successful TrachFlush activations from start of the study to

complete weaning from the ventilator, or a maximum of 7 days (primary).

Secondary outcome

Secondary endpoints include the total number of TrachFlush activations during

the same time window (all patients), and the exact amount of airway secretions

pushed past and above the cuff of the endotracheal tube (in patients with a

tube allows subglottal suctioning).

Study description

Background summary

In intubated and mechanically ventilated critically ill patients, removal of airway secretions is typically performed by tracheal suctioning, an intervention that is labor*intensive and very unpleasant for the patient. The current study tests the hypothesis that a novel secretion removal technology named TrachFlush, that pushes airway secretions past and above the cuff of the endotracheal tube, reduces the need for tracheal suctioning.

Study objective

The primary objective of this study is to evaluate whether use of the TrachFlush reduces the need for tracheal suctioning. In a selection of patients, one secondary objective is to ascertain the exact volume of airway

secretions that is pushed past and above the cuff of the endotracheal tube.

Study design

Open prospective intervention study.

Intervention

The attending nurses activate the TrachFlush when there are secretions present in the larger airways that need to be removed. If this results into a push of airway secretions past and above the cuff of the endotracheal tube, no further action is needed. If unsuccessful, the nurse will perform a standard tracheal suctioning procedure to remove the secretions. In a subset of patients with an endotracheal tube that allows subglottal suctioning, the exact amount of airway secretions present above the cuff will be measured each time the TrachFlush is used.

Study burden and risks

Inappropriate deflation or inflation of the endotracheal cuff by the TrachFlush could cause harm. However, the cuff pressure will be checked regularly, and if necessary corrected, at least every time the TrachFlush has been used. Patients may benefit from the intervention, as the need for tracheal suctioning may reduce.

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;
intubated with an endotracheal tube containing a cuff;
receiving invasive mechanical ventilation; and
expected to need invasive ventilation beyond the following calendar day at the moment of inclusion.

Exclusion criteria

age < 18 years;
known or suspected tracheal damage, e.g., after inhalation trauma, thorax trauma, or intubation trauma;
any condition for which deflation of the endotracheal cuff is deemed detrimental, e.g., in case high airway pressures are needed; and
any infection, or colonization with pathogens that require strict isolation of the patient.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-08-2021
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Trachflush technology
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-07-2021
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	NL75593.018.20