Evaluation of an on-demand humidifier in neuromuscular patients on chronic ventilatory support; a pilot study.

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Primary objective: To evaluate the optimum comfortable on-demand humidification doses for neuromuscular patients requiring chronic mechanical ventilation using subjective as well as objective measurements of the optimum comfort.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON46789

Source
ToetsingOnline

Brief title
On-demand humidifier in chronic ventilatory support

Condition

- Neuromuscular disorders

Synonym
Neuromuscular disease

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Research

Intervention

Keyword: chronic ventilatory support, Home mechanical venitlation, neuromuscular disease, on-demand humidification

Outcome measures

Primary outcome

To determine and evaluate the optimal amount of humidification doses delivered by the On-Demand humidification system in neuromuscular patients requiring home mechanical ventilation. The patient*s perception will be monitored with subjective as well as with objective measurements of the optimum comfortable on-demand humidification doses.

The primary hypothesis is that the perception and preference of the optimal amount of humidification provided by the on-demand humidification for subjects requiring mechanical ventilation will be better when compared to humidification supplied by their presently used humidifier or no humidification.
This hypothesis will be tested in the study by evaluating the optimum comfortable amount of on-demand humidification for the patient in a step by step increasing humidification test and evaluating patient*s perception with subjective measures (questionnaire based on Borg Scale, Visual Analog scale) as well as objective measures (e.g. heart rate,breathing rate, SpO2, transcutaneous CO2, number of mucus clearance events (recorded in test log).

Secondary outcome

Not applicable

Study description

Background summary

Mechanically ventilated patients require the inspired air to be humidified when the upper airway is bypassed by a tracheotomy. Patients being ventilated non-invasively for almost 24 hours need this humidification as well. The conventional heated humidifier generates water vapor near the ventilator. The water vapor and air mixture travel up the tube to the patient*s interface. Movement of the patient or the patient circuits often move the water condensate to the tracheal interface. This poses a serious health risk since the condensate inside the tubing is not sterile, and can re-enter the airway. The conventional heated humidifier method is also not practical for portable mechanical ventilators such as the Philips Respironics trilogy. The required battery for 8 hours of heated humidification would weigh about 12 pounds. Therefore, an on-demand humidification system has been built that delivers along nebulization only humidification when the patients breathes in. As the nebulizer systems have a low power consumption it opens the way to a portable humidification system. These nebulizers deliver also the humidification at room temperature in small quantities and therefore will reduce the risk of high amount of condensate that collects in the tubes and might enter the patient*s lungs.

The primary hypothesis is that the perception and preference of the optimal amount of humidification provided by the on-demand humidification for subjects requiring mechanical ventilation will be better when compared to humidification supplied by their presently used humidifier or no humidification.

Study objective

Primary objective: To evaluate the optimum comfortable on-demand humidification doses for neuromuscular patients requiring chronic mechanical ventilation using subjective as well as objective measurements of the optimum comfort.

Study design

In the pilot study, trained clinicians will set up participants, who already use a Trilogy Ventilator, with the on-demand humidification.
Prior to patient arrival, the system is cleaned according to the cleaning procedure (appendix 2) by Philips representatives, and prepared according to the manual.

At their arrival, the patient*s subjective well-being will be assessed using the hospital anxiety and depression scale(HADS) . Explicitly, the kind of humidification used by the subject on the way to the hospital (HME, for

example) and the subjective perception of the quality of this humidification will be asked for.
Before the test, the settings of the patients* Trilogy ventilator will be copied into the hospitals Trilogy ventilator by the clinician responsible for the test. Subsequently, the patient is disconnected from their Trilogy ventilator, and is connected to the hospital Trilogy ventilator.

The subjects will use the on-demand humidifier 2 X 2 hours. They start with the low dose for 2 hours. If the dose of humidification is to low, we stop directly and their conventional humidification being used while they are mobile, will be used 30 minutes. Finally the highest dose starts for 2 hours. If the dose of humidification is to low we stop directly and restart the conventional humidification and the pilot stops. The total time of participation has a maximum of 4,5 hours.

During this first phase of the study, objective measures of ventilator data, heart rate, breathing rate, SpO2, transcutaneous CO2, as well as the number of mucus clearance events will be collected. Also the FLIR E40bx Handheld infrared camera, used for optional thermogram of nose and mouth. will be used. Records images on local storage medium (SD card).
After each cycle the patient will be asked on his comfort level. At the end of the first phase the patient will be asked which humidification dose was most comfortable.

Intervention

The study starts with the recruitment, including explanation of the trial and signing the informed consent form, and testing the on-demand humidification devices in 10 neuromuscular patients requiring home mechanical ventilation. It starts with the first phase in the evaluation of the on-demand humidification amount that is optimum in the perception of the patient. After this optimum humidification amount has been identified, the patient will test this on-demand humidification quantity for 2 X 2 hours.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Anticipated clinical benefits
The benefit of the device under investigation is that the patient will have humidification while being mobile. The low power method of humidification makes it easier for the patient to be mobile and have active humidification at the same time.
Anticipated adverse device effects:
- Coughing due to airway irritation or excess mucus production.

- Transient lower oxygen saturation
- Transient increased carbon dioxide
- Transient Increased work of breathing
- Shortness of breath
- Anxiety.
Residual risks associated with investigational device [as identified in risk analysis report]
- Too much fluid nebulized. This is part of the investigation which means the staff should be alert on symptoms indicating this. For instance more frequent coughing of the patient.

Risks associated with participation in clinical investigation No additional device risks.
Burden associated with participation in clinical investigation -Single day-long hospital visit
-Potential mild discomfort during test (dry and/or cold air, coughing)
Possible interactions with concomitant medical treatments There are no interactions with concomitant medical treatments

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

1. Age > 18 of age; < 85 years of age
2. Participants with a neuromuscular disorder who:
a. Require 24 hour mechanical ventilation in some form through tracheostomy, mask or mouth piece
b. Can be ambulatory for at least a few hours during the day while using a heat and moisture exchange device (HME) or no humidification
c. Can part of the day use a heated pass-over humidification system while on their ventilator (overnight, for example).
3. Able to provide feedback/articulate via some form of communication
4. Patients using a Trilogy ventilator
5. Invasively ventilated patients that are willing to use a HME device on their way to participate in the study (from home to hospital).
6. Patients that are willing to participate and are able to consent and sign the informed consent form. (Patients with the functional capacity for medical decision-making).

Exclusion criteria

1. Clinically unstable, i.e.,
a. Acute respiratory failure
b. Participants with hypotension (defined as systolic blood pressure less than 90 mm Hg despite inotropic agents)
c. Uncontrolled cardiac ischemia or arrhythmias
d. Any participant determined as inappropriate for the study by the Principal Investigator
2. Patients suffering from metastatic or terminal cancer
3. Patients lacking the functional capacity for medical decision-making.

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):	12-01-2018
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	on-demand humidification
Registration:	No

Ethics review

Approved WMO Date:	20-09-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-05-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL62173.042.17
Other	Nummer volgt later