Phase 2 clinical feasibility study of a new Speaking Valve with a heat- and moisture exchanger (TW) for tracheotomized patients.

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The Purpose of the study is to investigate the clinical feasibility of the TW15 and TW22.

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

Summary

ID

NL-OMON38448

Source
ToetsingOnline

Brief title
Clinical feasibility of the TW

Condition

- Other condition
- Upper respiratory tract disorders (excl infections)

Synonym
airway opening, Tracheotomy

Health condition

tracheostomy

Research involving
Human

Sponsors and support

Primary sponsor: Atos Medical AB
Source(s) of monetary or material Support: ATOS Medical BV

Intervention

Keyword: HME, Speaking valve, Tracheostomy

Outcome measures

Primary outcome

Exploratory - none. Exploratory parameters are: lungfunction (cough, mucus),

breathing, aspiration, speaking, olfaction, use, maintenance and overall

statisfaction of the patients.

Secondary outcome

N.A.

Study description

Background summary

Title
Phase 2 clinical feasibility study of a new Speaking Valve with a heat- and moisture exchanger (TW) for tracheotomized patients.
Background and Rationale
In tracheotomized patients, a tracheostomy tube is inserted in a surgically created opening (a tracheostoma) in the neck. The main reason for this procedure is the presence of an upper airway obstruction that is causing difficulties breathing. Underlying medical causes are diverse and may for example be neurological, oncological, or resulting from trauma.

Tracheotomized patients mainly breathe through the tracheostomy tube. Depending on the level of upper airway obstruction some air exchange may take place through the upper airways as well. To be able to speak, a tracheotomized patient needs to occlude the tracheostomy tube, either directly with a finger on the opening of the tube, with a finger on a Heat and Moisture Exchanger (HME), or hands free using a so-called speaking valve. A speaking valve contains a membrane that only opens when the patient inhales; it remains closed

during exhalation which then allows redirection of the exhaled air through the upper airways allowing speech. When breathing in through the tube, the upper airways are bypassed and the inhaled air remains unconditioned. An HME compensates for this. Exhaled air conditions the HME and upon inhalation the HME conditions the inhaled air.

Technically, an HME functions when exhaled air passes the HME and conditions the HME media. A bias-closed speaking valve (i.e. a Speaking Valve that only opens upon inhalation) redirects air through the upper airways. Hence, when using a bias-closed Speaking Valve, the exhaled air would not pass through the HME and would not condition the HME. Currently, there are no devices commercially available for tracheostomy patients that combine both functions.

The TW, however, combines a bias-closed Speaking Valve with an HME. The device can be switched from HME mode to speaking mode by a simple twisting motion, allowing the patient to benefit both from the HME function (when in HME mode) and the Speaking function (in Speaking mode).

Due to the uniqueness of the device for this patient population, a clinical feasibility study has been conducted at the UMCG to explore the limitations and advantages of the performance of the TW Speaking Valve used in combination with a TW22 HME cassette in 14 patients. The outcomes of this early feasibility study were generally positive, and have led to some design changes to the TW Speaking Valve. The current study aims to investigate the redesigned TW Speaking Valve, now in combination with both a 15 mm and a 22 mm HME cassette, to allow use with tracheostomy tubes with a 15 mm and a 22 mm connector.

Study objective

The Purpose of the study is to investigate the clinical feasibility of the TW15 and TW22.

Study design

The investigation will be a non-randomized, prospective study in which the patient will act as his own control. All patients are intended to use the TW device for two weeks: one week with the 15 mm HME cassette and one week with the 22 mm HME cassette. After two weeks, if the patient wishes to do so, the patient can continue to use the TW device with the HME cassette of their choice. The study will take a maximum of three months.

Intervention

The use of the TW device for a period of 2 weeks, with the option to continue using it until 3 months. After these three months, patients can continue to use the device for a total of one year if the device is not yet commercially

available.

Study burden and risks

No new risks have been identified related to the new TW device.
It is expected that the study may be of some burden to some patients due to the required visit to the hospital and the meetings on the telephone. The patient information and informed consent procedure will take about 15 minutes. Each contact moment is expected to take about 45 minutes. Patients that wish to continue using the device after two weeks will have a contact moment every four weeks until week 14 to record any adverse events/adverse device effects and changes in medication. At week 14 the patient will be asked to complete structured questionnaires. If the patient continues using the device after week 14, there will be a monthly follow-up to record any adverse events/device effects and changes in medication.

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

• is 18 years or older;
• has a tracheostomy;
• is spontaneously breathing;
• has a cuffless tracheostomy tube;
• has a tracheostomy tube with inner- and outer cannula;
• currently uses an HME and/or speaking valve.

Exclusion criteria

• is unable to handle or remove the device him/herself when needed, e.g. has decreased level of cognition or reduced mobility of the arms and/or hands;
• is mechanically ventilated in any way;
• has a tidal volume of less than100 ml;
• is suffering from severe aspiration;
• is laryngectomized; the device will block the possibility to exhale if speaking mode is unintentionally activated;
• has severe upper airway obstruction, this may cause air trapping;
• has thick and copious secretions, which might block the device.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2013

Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	HME/Speaking valve (TW)
Registration:	No

Ethics review

Approved WMO Date:	04-09-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-12-2013
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	NL43634.042.13