Short-term clinical feasibility of a new Speaking Valve with a heat- and moisture exchanger (TW22) for tracheotomized patients.

Published: 14-05-2012
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To investigate the clinical feasibility of the TW22.

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

Summary

ID

NL-OMON37865

Source
ToetsingOnline

Brief title
Clinical feasibility of the TW22

Condition

- Other condition

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 AB

Intervention

Keyword: HME, speaking valve, tracheostomy

Outcome measures

Primary outcome

The design of the study is in line with the early nature of the investigation

and is observational. There are no specific outcome measures or endpoints.

The parameters that are assessed are in line with the parameters that have been

reported in the literature to possibly be affected by the use of an HME or

Speaking Valve by tracheotomized patients (speaking, breathing, pulmonary

symptoms, swallowing, olfaction).

Secondary outcome

N.A.

Study description

Background summary

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 a 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 without a finger using a so-called speaking valve. A bias-closed

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 tracheostomy 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.
Currently, there are no devices commercially available for tracheotomized patients that combine both functions. Technically, an HME functions when conditioned by exhaled air. A bias-closed speaking valve redirects air through the upper airways. Hence, when using a Speaking Valve, the exhaled air would not pass through the HME and would not condition the HME.
This problem is overcome in the TW22. The TW22 combines a Speaking Valve with an HME. The device can be switched from HME mode to speech mode by a simple twisting motion, allowing the patient to benefit both from the HME function (when in HME mode) and the Speech function (in Speech mode).
Due to the uniqueness of the device for this patient population, a clinical feasibility study is proposed to explore the limitations and advantages of the performance of the TW22 in 15 eligible patients.

Study objective

To investigate the clinical feasibility of the TW22.

Study design

A non-randomized, prospective, clinical investigation to evaluate the clinical feasibility TW22 and explore its limitations and advantages.

Intervention

The use of the TW22

Study burden and risks

No new risks have been identified related to this new adhesive.
It is expected that the study may be of some burden to some patients due to the 2 required visits. The patient information and informed consent procedure will take about 15 minutes. Each visit is expected to take about 45 minutes.
Patients that choose to stay in the study and continue use of the device will need to visit the hospital monthly for brief follow-up and to receive a new TW22 device.

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

18 years or older;
have a tracheostomy;
sufficient cognitive ability for handling the TW22;
sufficient manual dexterity for handling the TW22;
are spontaneously breathing;
Have a tidal volume of 250 ml or more;
have a cuffless tracheostomy tube
have a tracheostomy tube with inner- and outer cannula;
have an inner tube with a 22mm connector;
are currently using an HME and/or Speaking Valve;
adequate upper airway.

Exclusion criteria

use of a too wide non fenestrated tube that does not allow air passage around the tube;
laryngectomized;
mechanically ventilated;
severe airway obstruction;
severe aspiration;
thick and copious secretions.

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):	08-06-2012
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	HME/Speaking valve (TW22)
Registration:	No

Ethics review

Approved WMO

Date:	14-05-2012
Application type:	First submission
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	NL38880.042.12

Study results

Date completed:	28-12-2012
Actual enrolment:	14