The effect of Heat and Moisture Exchangers on tracheal mucociliary clearance in laryngectomized individuals.

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Primary objective is to measure the effect of the use of different HMEs with different fluid exchange, and the effects of changing between HME routines, on the tracheal mucociliary transport in laryngectomered individuals.Secondary objectives are to…

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

Summary

ID

NL-OMON51169

Source
ToetsingOnline

Brief title
HME effect on lung clearance

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Larynx cancer, Larynx removal, Total laryngectomy

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Unrestricted research grant Atos Medical AB Zweden

Intervention

Keyword: Heat and Moisture Exchanger, Pulmonary function, Total laryngectomy

Outcome measures

Primary outcome

Scintgraphy acquisition from which the tracheal mucus transport velocity will

be calculated

Secondary outcome

Tally sheets

CASA-Q

Study description

Background summary

The aim of the research is to gain more insight into the physiological effects of HME-routines with different fluid exchange, and the effects of changing between HME routines, on the tracheal climate after total laryngectomy. It is hypothesized that there is a positive relationship between the fluid exchange of an HME and the mucociliary transport in laryngectomees. This study could provide a basis for new developments in HMEs to further reduce airway problems in laryngectomized people.

Study objective

Primary objective is to measure the effect of the use of different HMEs with different fluid exchange, and the effects of changing between HME routines, on the tracheal mucociliary transport in laryngectomered individuals.
Secondary objectives are to investigate the relationship between the tracheal mucociliary transport, the clinical data on (experienced) lung complaints and HME type and to develop a gold standard to test the HME effect on mucociliary clearance.

Study design

To investigate the effect of HME use of different HME types with different fluid exchange on the tracheal climate in vivo, 20 total laryngectomees will be

asked to use three different types of HMEs (1 control HME and 2 intervention HMEs with different fluid exchange activity), each during two weeks, in combination their normal daily routine for confirming these HMEs. For this study, the participants have to come to the hospital three times (duration per visit: 1.5 hours). During the first visit, a tally sheet and CASA-Q questionnaire is filled out (about experienced lung complaints) and a baseline scintigraphy acquisition is made. Thereafter, the participant will return for a scintigraphy acquisition two more times, each after a period of two weeks in which they use a different type of intervention HME. Based on this scintigraphy acquisition, the mucociliary transport of mucus can be determined, thus quantifying the effect of the different HME types on the tracheal climate.
In addition to the scintigraphy acquisitions, as a clinical outcome measure, participants will be asked to record the frequency of coughing and coughing up phlegm on a tally sheet and CASA-Q after each two-week period for 48 hours.

Intervention

Three different types of HMEs can be used (1 control HME and 2 intervention HMEs with different moisture exchange effect)

Study burden and risks

Participants may experience more mucus / coughing through the use of the HME intervention

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

- Laryngectomized patient
- 18 years or older
- Daily HME user
- At least 6 months post-surgery
- Stable pulmonary condition
- Be proficient in Dutch
- Signed informed consent

Exclusion criteria

- Medical problems prohibiting the use of HME
- Active recurrent or metastatic disease or lung cancer
- Clinical signs of pulmonary or tracheal infection less than 6 weeks prior to study participation
- Inability of lying still in supine position during 45 minutes
- Use of short-acting bronchodilators less than six hours prior to study
- Use of long*acting bronchodilators less than twenty four hours prior to the study

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-10-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Heat and Moisture Exchanger
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-06-2021
Application type:	First submission
Review commission:	METC NedMec

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	NL76014.031.20