Short Term Effect of a Heat and Moisture Exchanger on Tracheal Mucociliary Clearance in Laryngectomized Individuals

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Primary: Assessment of the short-term effect of a Heat and Moisture Exchanger on tracheal mucociliary clearance in laryngectomized individuals. Secondary: The relationship between clinical assessment, ciliary activity and mucociliary clearance.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON36030

Source
ToetsingOnline

Brief title
Short term effect of HME on mucociliary clearance

Condition

- Tissue disorders NEC
- Lower respiratory tract disorders (excl obstruction and infection)
- Respiratory tract therapeutic procedures

Synonym
Mucociliary clearance

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W,Atos Medical ,Unrestricted research grand atos medical

Intervention

Keyword: Heat and Moisture Exchanger, Mucociliary Clearance, Total Laryngectomy

Outcome measures

Primary outcome

Tracheal mucus transport velocity.

Secondary outcome

Study specific questionnaire, tally sheet and ciliary activity.

Study description

Background summary

Laryngectomized patients suffer from pulmonary problems due the bypass of the upper airway tract. This new breathing situation leads to loss of optimal conditioning (moistening and warming) of the breathing air. Improvements of the reduced air-conditioning after total laryngectomy can be achieved by application of a Heat and Moisture Exchanger (HME). In theory it is likely that an HME not only improves tracheal climate, but also positively influences tracheal mucociliary clearance. Restored tracheal mucociliary clearance could be responsible for further reduction of the respiratory problems. However, the hypothetical short term HME effect on mucociliary clearance has never been studied in laryngectomized patients. The first step is to determine whether the short-term effect of the use of an HME on tracheal mucociliairy clearance is measurable and significant.

Study objective

Primary: Assessment of the short-term effect of a Heat and Moisture Exchanger on tracheal mucociliary clearance in laryngectomized individuals. Secondary: The relationship between clinical assessment, ciliary activity and mucociliary clearance.

Study design

Tracheal mucus transport measurements are performed using scintigraphy. A

droplet of radio labelled 99mTc Nanocolloid and methylene blue is placed on the tracheal epithelium above the carina via the permanent tracheostoma. The displacement of radioactivity is measured using a gamma camera. First, a baseline measurement is performed to select patients with initial mucus transport velocity of at least 1 mm/min for statistical calculations. After a three-week period, the baseline measurement is followed by a randomized second and a third measurement (with and without HME). The control measurement is performed after continuously breathing with HME. Measuring without HME is performed after exposure of one hour breathing without HME. Tracheal brush biopsy is performed after the first and last measurement for ciliary activity assessment. A study specific questionnaire will be obtained at the first visit. Frequency of coughing and mucus expectoration will be assessed using tally sheets before and after every measurement.

Intervention

Removal of HME during one hour prior to the measurement.

Study burden and risks

The subjects will experience no pain and very little discomfort from the measurements. The intervention and measurement do not affect the respiratory functioning. The amount of radioactivity is minimal and will not be absorbed by the body, but will be cleared through the tracheostoma within one day.

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 patients:
- At least 1 year post surgery
- Stable pulmonary condition
- In complete remission
- Using Xtra Moist Provox HME (Atos Medical)
- Written Informed consent

Exclusion criteria

- 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
- Mucus flow velocity of less than 1 mm/min will be excluded from further scintigraphy measurements after baseline measurement.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-11-2011
Enrollment:	25
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	25-08-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-05-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL37349.031.11