The influence of the new HME Energy on physical activity and patient satisfaction in laryngectomized patients

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-To describe the differences in the parameters of physical exertion during physical activity with two different HMEs in both a lab and daily life setting-To asses patients* satisfaction with both types of HMEs

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Soft tissue neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON49248

Source
ToetsingOnline

Brief title
HME Energy

Condition

- Soft tissue neoplasms malignant and unspecified
- Upper respiratory tract disorders (excl infections)
- Head and neck therapeutic procedures

Synonym
Physical consequences of a laryngectomy

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: NKI-AvL

Intervention

Keyword: HME, Laryngectomy, Physical activity, Quality of life

Outcome measures

Primary outcome

-The changes in heart rate (HR) and respiratory rate (RR) relative to physical

activity levels in daily life activities

-Changes in VO2 uptake and CO2 clearance from gas analysis during submaximal

exercise testing

-Self-reported measures of satisfaction and comfort (questionnaires), and Borg

scale for perceived levels of exertion during exercise testing

Secondary outcome

Not applicable

Study description

Background summary

Members of this study population are less likely to meet daily exercise guidelines for a multitude of reasons, one of which being the breathing resistance imposed by heat and moisture exchangers (HMEs). With the Energy HME, which has a goal of reducing breathing resistance during physical activity, the hope is to make physical activity more attainable for laryngectomized individuals. This study aims to asses how the parameters of physical exertion vary during day to day physical activities as well as during more intensive bouts of physical activity in individuals using an HME, and to explore how these parameters differ when using the Energy HME as compared to an individual*s regularly used HME. With physical activity more comfortable and doable for individuals, it will be possible to design more effective exercise training in the future and therefore enhance the overall health of this population.

Study objective

-To describe the differences in the parameters of physical exertion during physical activity with two different HMEs in both a lab and daily life setting
-To asses patients* satisfaction with both types of HMEs

Study design

Prospective, single group randomized cross-over observational study

Intervention

All included subjects will participate in all testing conditions. They will undergo submaximal exercise testing as well as observation for extended periods using 2 different HME models: their regular daily HME and the Energy HME.

Study burden and risks

We do not foresee any risks to be associated with this study as both treatment conditions have undergone the individual approval process and will be used according to their intended use. There is burden on the participants as they will be required to attend 4 appointments, fill out questionnaires on 3 separate occasions, participate in submaximal exercise testing, wear a heartrate and physical activity monitoring device, and change out monitoring devices on 3 separate occasions.

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

* Undergone a total laryngectomy
* Be a daily HME user
* Maintain a fairly active lifestyle
* Be proficient in Dutch

Exclusion criteria

* Lead a sedentary life
* Are wheelchair bound
* Have known cardiac issues
* Lack of access to WIFI in the home

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-11-2020
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Heat and Moisture Exchangers (HME) (Energy;Go;Home)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-07-2020
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	25-02-2021
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	16-04-2021
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL72840.031.20