

# 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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Soft tissue neoplasms malignant and unspecified
<b>Study type</b>	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 VO<sub>2</sub> uptake and CO<sub>2</sub> 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 assess 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 assess 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 heart rate and physical activity monitoring device, and change out monitoring devices on 3 separate occasions.

## **Contacts**

### **Public**

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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