The effectiveness of device-driven Expiratory Muscle Strength Training (EMST) in total laryngectomy patients; A pilot study.

Published: 27-02-2017
Last updated: 11-04-2024

The main purpose of this study is to examine the effects of expiratory muscle strength training (EMST) in subjects who have undergone a total laryngectomy. In this pilot study outcomes in pulmonary function, functional exercise capacity, vocal...

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

Summary

ID

NL-OMON45719

Source
ToetsingOnline

Brief title
EMST in total laryngectomy patients.

Condition

- Other condition
- Upper respiratory tract disorders (excl infections)

Synonym
Pulmonary functioning, reduced cough strength

Health condition

Stemproblemen

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Expiratory Muscle Strength Training (EMST), Pulmonary functioning, Total laryngectomy, Voice outcomes

Outcome measures

Primary outcome

Maximum Expiratory Pressure en Peak Expiratory Flow.

Secondary outcome

Spirometry which revelas Vital capacity (VC), forced expiratory volume in the

first second (FEV1) and, mean expiratory flow (MEF). Cardio Pulmonary Exercise

Test (CPET) which includeds measurements of breath-by-breath minute ventilation

(VE), oxygen uptake (VO2), carbon dioxide production (VCO2), and RER

(VCO2/VO2).

Voice recordings to obtain maximum phonation time (sec) and range in Hz (high -

low) and dB (soft - loud).

Borg Ratings of Perceived Exertion

Modified Borg Dyspnoea Scale

Short Fatigue questionnaire

Linear Analogue Self Assessments

Clinical COPD Questionnaire

Voice Handicap Index 10 item version

Study description

Background summary

After a total laryngectomy (TL) patients experience problems with speaking, coughing and mucus clearing due to their altered anatomy. Removal of the larynx alters airway configuration, redirecting pulmonary airflow through the neck via a tracheostoma. Air entering the lungs by way of the stoma is not warmed and humidified by the nose and upper respiratory tract, contributing to increased mucus production (1, 2). Impaired cough function occurs following TL. Vocal functioning after TL is an important factor in quality of life outcomes. The majority of patients who undergo TL rehabilitate their vocal functions by speaking with a voice prosthesis, also called tracheoesophageal Speech (TE-speech). In TE-speech pulmonary driven speech is re-established, phonation length and vocal range is limited in this patient group.
Expiratory muscle strength training (EMST) is a behavioural, device-driven treatment for improving expiratory pressure generating capacity. Evidence of its benefits is assessed in a group of healthy elderly, a group with Parkinson disease and in a group of stroke patients. In this study we would like to assess the effects of EMST in the population of TL patients.

Study objective

The main purpose of this study is to examine the effects of expiratory muscle strength training (EMST) in subjects who have undergone a total laryngectomy. In this pilot study outcomes in pulmonary function, functional exercise capacity, vocal functioning and participant*s quality of life will be assessed.

Study design

In this prospective randomized case series twelve TL patients from the Netherlands Cancer Institute will be included. Patients will be randomized in two groups stratiefied by age, each of six individuals. Both groups start a four week training period with the EMST-device. One training session per day, five days a week. A training session contains five sets of five forced exhalations with EMST-device. After the four week training period group 1 stops training and hands in the EMST-device. Group 2 continues training at a maintenance dose for another four weeks. Subjects log their training sessions in a patient diary. During the study period the patient frequently visits the hospital to adapt the device. At baseline, after four weeks and after eight weeks assessments are performed to obtain information about pulmonary function, functional exercise capacity, voice outcomes and quality of life. By analyzing

the functional outcomes and quelity of life possible benefits of EMST training is will be assessed.

Intervention

Group 1 (n=6) Four weeks of EMST-training, four weeks no training.
Group 2 (n=6) Four weeks of EMST-training, four weeks continued training on maintainence dose.
Both groups perform the first four weeks five training sessions a week, five sets per training session containing five forced exhalations. The maintainence dose contains two training sessions a week, five sets per training session containing five forced ehalations.

Study burden and risks

No serious adverse events are associated with participation. Test procedures involve forceful breathing which might cause dizziness or in rare cases bradycardia. A four to eight week EMST training program has to be performed, during this period the participant has to fill in a diary. Participants need to visit the hospital six times during this period of eight weeks for pulmonary testing, monitoring the training and controlling the device. At three time points more extensive pulmonary and vocal tests are carried out and the participant is asked to fill in questionnaires. The treatment device is CE certified and assessed in different populations, no excessive risks and burden are mentioned. The burden and risks associated with this device and training period can be justified because of the fact that the training program might improve pulmonary functioning, voice and therefore quality of life.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 years or older
Male
Undergone TL
At least 6 months post TL
At least 6 months post-operative (chemo)radiotherapy
Signed informed consent

Exclusion criteria

Currently undergoing chemotherapy +/- radiation therapy
Positive past history of lung cancer or tuberculosis
Reoccurrence of head and neck cancer
History of abdominal hernia
Uncontrolled or untreated hypertention
No heart attack in the previous year
Unable to understand the patient information.
Unable to comprehend and use of the device (e.g. Alzheimer* s disease, Korsakov).
Physically unfit to use the device (e.g. neurological deficit).
Unwilling or unable to provide informed consent or do not possess the ability or willingness to comply with study-related procedures.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2017
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Expiratory Muscle Strength Trainer
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-02-2017
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	24-03-2017
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	NL60167.031.16