The Swallowing Exercise Aid in Total Laryngectomy: Feasibility, Adherence and a Multidimensional Assessment of Functional-, Physical-, and Patient-reported outcomes

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

Summary

ID

NL-OMON50048

Source
ToetsingOnline

Brief title
SEATTLE

Condition

- Other condition

Synonym
dysphagia, Larynx extirpation

Health condition

Hoofdhalskankerpatienten die een totale laryngectomie hebben ondergaan

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: MRI, Swallowing training, Total laryngectomy

Outcome measures

Primary outcome

This study has a multidimensional assessment approach, including feasibility

and adherence, physical outcomes, functional outcomes, and patient-reported

outcomes. In this study, measures of interest are muscle strength,

manofluorography, manometry, voice recordings, dynamic range of voice, maximum

fonation time, questionnaires, and information from the electronic medical

files.

Secondary outcome

Secondary: (Multidimensional Evaluation)

Physical outcomes:

- Strength measurement (IOPI, dynamometer)

- Manofluorography

- Pressure measurement during breathing and vocalization (manometry)

Functional Outcomes:

- Voice recordings

- Mouth opening

Subjective outcomes:

- Questionnaires on Quality of life, swallowing problems, voice problems,

participation

Study description

Background summary

Total laryngectomy (TL), implicating surgical removal of the larynx, is the operation of choice in patients with advanced laryngeal or hypopharyngeal cancer. Functional disabilities associated with TL include impairment of swallowing, speech, olfaction, and taste. Muscle strength, muscle coordination, and pressure build-up are essential factors for swallowing and tracheoesophageal speech. Research has shown that TL negatively influences the patients* pressure build-up at the base of the tongue and coordination of muscular contraction in the neopharynx. The Swallow Exercise Aid (SEA) is developed as an exercise tool that activates and strengthens the suprahyoid and pharyngeal muscles relevant for swallowing function. The feasibility and adherence were considered good in healthy senior adults and head and neck cancer patients with chronic dysphagia. Following these positive results, the feasibility, adherence, and effectiveness of its use for rehabilitation of swallowing and tracheoesophageal speech will be studied in patients with altered anatomy because of TL.

Study objective

The primary objective is to evaluate the feasibility and adherence of 6 weeks of rehabilitation with the SEA in participants who underwent TL. The secondary objective is to examine if the SEA is an effective tool to improve swallowing function and tracheoesophageal speech. The outcomes include functional (swallowing efficiency, vocal functioning) and physical (intra-pharyngeal pressure) outcomes, patient-reported complaints, and quality of life.

Study design

The proposed study is a pilot study and includes a prospective feasibility study involving one training group, six weeks of training and three moments of assessment.

Intervention

All participants have to train three different strengthening exercises with the

SEA three times a day, including the Chin Tuck against resistance (CTAR+), Jaw Opening against resistance (JOAR+), and the Effortful swallow exercise (ES+) for six weeks.

Study burden and risks

Participating in this study and training with the SEA might improve swallowing function and voice quality. These improvements may lead to enhance the quality of life. Muscular pain or muscular exhaustion might be the only risk associated with participation in this study. The assessments contain radiation and manometry in which nose bleeding is a minimal risk.

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

• >= 18 years or older
• Undergone a TLE
• At least six months post TLE
• At least six months postoperative (chemo-) radiotherapy (if applicable)
• Using Tracheoesophageal speech
• Oral intake of a modified diet (FOIS 2 - 6) or who experience swallowing problems
• Signed informed consent

Exclusion criteria

• Unable to understand the patient information
• Unable to understand the informed consent
• Unable to comprehend and use the SEA
• Unable or unwilling to provide informed consent
• Neuro-degenerative diseases, for instance, dementia, Parkinson, Korsakov

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2022
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Swallowing Exercise Aid (SEA)

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-10-2021
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	NL78528.031.21

Study results

Date completed:	16-10-2023