MRI Assessment of Muscle Activation with the Swallow Exercise Aid and Conventional Exercises after total laryngectomy: an explorative biomechanical study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON49905

Source
ToetsingOnline

Brief title
SEAM

Condition

- Other condition

Synonym
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 A.B. Sweden

Intervention

Keyword: MRI, Swallowing training, Total laryngectomy

Outcome measures

Primary outcome

The main study parameter contains the change in T2 value of possible involved

muscles of the neopharynx at rest and after exercise. Muscles included are the

masticatory muscles, intrinsic and extrinsic tongue muscles, supra- and

infra-hyoid muscles, palatal muscles, and pharyngeal muscles.

Secondary outcome

anatomical variations

Study description

Background summary

After total laryngectomy (TL), 72% of patients report long-term swallowing problems. The altered anatomy, in which some crucial muscles involved in swallowing are removed or transected, results in an altered transit of the bolus through the pharynx, stenosis of the newly created pharynx (neopharynx), poor pressure build-up at the tongue base, and loss of coordinated muscular contraction in the neopharynx. Different swallow exercises with and without resistance, using the swallow exercise aid (SEA), have shown to be effective in restoring swallowing function in patients with oropharyngeal dysphagia. However, these exercises have never been evaluated in the TL population. Due to the altered anatomy, information about which muscles are activated by conventional exercises and exercises against resistance is lacking. We

hypothesize that training with the SEA activates the same muscles as traditional exercises. However, we assume that training with the SEA leads to more intense muscle activation.

Study objective

This study aims to visualize the muscles activated during standard exercises performed with and without the SEA using T2 mapping with MRI in patients who underwent TL. Other aims of this study focus on anatomical variations between the TL patients and compare these variations with swallowing complaints and surgical techniques.

Study design

Pilot study with a pre- and post-test, explorative biomechanical design

To analyze which muscles are activated by conventional swallow exercise training and swallow exercise training against resistance with the metal-free plastic SEA, the MRI will be used. Dry swallow and six exercises will be investigated on the same day in a fixed order with resting periods to avoid the effects of the previous exercise disturbing the results of the next exercise. The exercises in the specified order are 1) Dry swallow, 2) Conventional Effortful Swallow (cES), 3) Masako, 4) Shaker, 5) Chin Tuck against resistance (CTAR+), 6) Jaw Opening against resistance (JOAR+) and 7) Effortful Swallow against resistance (ES+). Firstly, the participant will be asked to relax in a supine position, and the first MRI scan will be done. Then the participant is asked to perform one of the exercises until exhaustion, meaning that the participant cannot perform another repetition of the exercise. Directly after completing the exercise until exhaustion, the second MRI scan will be made.

Study burden and risks

The burden consists of the time it takes to participate: approximately 140 minutes. The risk of participating in this study is mainly muscle pain after performing swallowing exercises until exhaustion. Health risks do not accompany the MRI itself. The participant will not benefit from participating in this study. However, the results of this study are relevant for TL participants. This information can be used to optimize the training program.

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
- Complete remission
- 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
- Patients who meet contraindication for MRI, such as the presence of metallic implants, pacemakers, or claustrophobia

- Patients who use the Provox® ActiValve®

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-07-2022
Enrollment:	6
Type:	Actual

Medical products/devices used

Generic name:	Swallow Exercise Aid (SEA)
Registration:	No

Ethics review

Approved WMO

Date:	15-10-2021
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	NL78467.031.21