Phase-2 clinical trial on the treatment of chronic dysphagia in head and neck cancer patients with dedicated strengthening exercises using the Swallow Exercise Aid

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Primary objective: effectiveness of the SEA exercises in HNC patients with chronic dysphagia, following an exercise protocol of 6 weeks.Secondary objective: feasibility/compliance of the SEA exercises in HNC patients with chronic dysphagia, during...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON42230

Source
ToetsingOnline

Brief title
Strengthening exercises in head and neck cancer patients with dysphagia

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
Dysphagia, swallowing impairment

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Dysphagia, Head and Neck cancer, Strengthening Exercises, Swallow Exercise Aid

Outcome measures

Primary outcome

Effectiveness endpoints:

- Swallowing muscle strength (in Newton)

o Maximum chin tuck strength

o Maximum jaw-opening strength

- Tongue strength and endurance (in kilopascal)

- Videofluoroscopy swallowing parameters

o Swallowing transport times (in seconds)

o Anterior/superior hyoid bone displacement (in millimetres)

o Presence of penetration/aspiration

o Presence of contrast residue

Feasibility/compliance endpoints:

- Feasibility of the SEA exercises (study-specific questionnaire)

- Compliance of the SEA exercises (study-specific questionnaire)

Secondary outcome

Additional endpoints:

- Maximum mouth opening (in millimetres)

- Tube feeding dependency

- Oral intake / nutritional status (FOIS score)

- Weight and BMI

- Subjective perspective on swallowing function (SWAL-QOL questionnaire)

Study description

Background summary

Swallowing requires a complex interaction between various muscles in the tongue, floor of mouth, pharynx, and larynx. This complex physiologic course of muscle events and interactions is at risk in patients treated for head and neck cancer (HNC). Swallowing impairment/dysphagia is not uncommon in these patients. It can be caused by the tumor extension itself, but maybe even more so, because of surgical resection and trauma as well as tissue reactions resulting from (organ preserving) chemoradiotherapy (CRT). Tongue strength, which also plays a role in the swallowing physiology, is reduced in patients treated with primary CRT. When, because of pain and dysphagia during treatment, the swallowing muscles are no longer actively used, the swallowing muscles might eventually atrophy, which further limits swallowing function. Implementation of preventive swallowing exercises has been demonstrated to prevent this so-called *non-use atrophy* in patients with advanced HNC undergoing CRT, to improve post-treatment swallowing function and quality of life. Based on the positive experiences with the TheraBite as a preventive exercise tool with good compliance, a new Swallow Exercise Aid (SEA) was developed, with the aim to overcome persistent/therapy-resistant swallowing problems. The effectiveness and feasibility of a SEA-based exercise protocol recently has been demonstrated in a prospective study in senior healthy subjects. Compliance appeared to be high (86%) and there was a significant increase of swallowing muscle strength and volume, anterior tongue strength, and some increase in mouth opening after six weeks of extensive swallowing training. Following these positive results, the effectiveness and feasibility of this SEA-based exercise protocol will now be studied in HNC patients with chronic/therapy-resistant dysphagia, who all have feeding tube dependency and/or high risk for developing aspiration pneumonia, despite routine previous swallowing exercise programs.

Study objective

Primary objective: effectiveness of the SEA exercises in HNC patients with chronic dysphagia, following an exercise protocol of 6 weeks.

Secondary objective: feasibility/compliance of the SEA exercises in HNC patients with chronic dysphagia, during the 6 weeks exercise regimen.

Study design

Uncontrolled, prospective clinical cohort study.

Intervention

Intervention: There are the three strengthening exercises to be performed with the Swallow Exercise Aid:
1. Chin tuck against resistance (CTAR) exercise
2. Jaw opening against resistance (JOAR) exercise
3. Effortful swallow exercise

Exercise and assessment protocol:
The (isokinetic and isometric) strengthening exercises are performed 3 times per day (15-20 minutes) during 6 weeks.
All patients will be asked to record their performances by using tally sheets in a special exercise log.

Also see the exercise protocol for more detailed instructions.

Study burden and risks

The general benefit of using the SEA is the possibility to improve swallowing function and to overcome dysphagia (i.e. tube feeding dependency). Foreseeable disadvantages may be pain, itchiness, or irritated skin (rash) at the chest due to compression of the chest bar onto the sternum, or at the chin due to compression of the chin bar. Also complaints of discomfort or pain in/around the jaw joint (muscle ache) may occur during the exercise period with the use of the SEA. However, based on the experiences with the SEA in senior healthy subjects, the surmountable burden which occurred was transient. Nevertheless, in case of (severe) muscle aches, the patient will be instructed to reduce the force required to press the chin bar onto the chest bar.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL

Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients who have been treated successfully with concurrent chemoradiotherapy or radiotherapy alone for head and neck cancer, for at least 1 year ago;
- Patients who are diagnosed with chronic (therapy-resistant) dysphagia for at least 1 year:
o Presence of penetration and/or aspiration on recent (< 3 months) videofluoroscop; and/or
o Seriously limited intake of a normal diet;and/or
o Presence of a (nasogastric or percutaneous) feeding tube; and/or
o Occurrence of recurrent (>= 1 during the last year) aspiration pneumonia; and
o Unresponsive/refractory to regular logopaedic swallowing therapy;
- Patients who are able and willing to perform the exercises with the Swallow Exercise Aid for 6 weeks.

Exclusion criteria

- Patients treated surgically for head and neck cancer (except for any kind of neck dissection);
- Patients with recurrent or residual head and neck cancer disease;
- Patients unable to comprehend the function of the Swallow Exercise Aid;
- Patients physically unfit (e.g. due to the occurrence of a tracheotomy) or unwilling to use the Swallow Exercise Aid daily;
- Patients living abroad.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-04-2015
Enrollment:	20
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	09-01-2015
Application type:	First submission
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	NL51087.031.14