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Respiratory swallowing therapy in patients with radiation associated dysphagia

Submission date
24/02/2025

Recruitment status
Recruiting

Registration date
28/02/2025

Overall study status
Ongoing

Last Edited
28/02/2025

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Head and neck cancer (HNC) is worldwide a highly prevalent disease. Approximately one fifth of newly diagnosed patients are at risk to develop oropharyngeal dysphagia. The main clinical symptoms of dysphagia are aspiration (i.e. food entering the airway) and residue (i.e. food that stays behind in the oral cavity, pharynx or larynx). Organ sparing treatment modalities, namely concomitant chemoradiotherapy (CCRT) and radiotherapy (RT), are standard care in patients with primary HNC. Despite continuous improvements and refinements of these treatments, scientific studies show that more than 50% of these patients suffer from treatment related dysphagia or radiation associated dysphagia (RAD). RAD can occur as an acute side effect of CCRT and RT but it can develop to a chronic condition (C-RAD), with up to 40% of patients presenting with dysphagia after (several years of) treatment. RAD is one of the most serious and disabling complications in HNC survivors. It has devastating consequences on the patient's health and well-being, including significantly reduced quality of life, malnutrition, dehydration and aspiration pneumonia and contributes consequently and significantly to non-cancer related mortality in this population.

Recently, there has been increasing clinical and scientific evidence for the positive effect of intensive swallowing rehabilitation on RAD. Training swallowing related muscles is an important strategy in the treatment of RAD. However, an underexposed factor is the coordination of swallowing, more specifically the skills to optimize the coordination between breathing and swallowing. Both functions use the same neural networks in the brainstem and cortex allowing for the tight coupling between their central control of these vital functions. During normal swallowing, inhalation is briefly interrupted by laryngeal closure to prevent aspiration of the bolus into the respiratory tract. Research shows that in typical respiratory swallow patterns (RSP), swallowing occurs during the expiratory phase of breathing or in other words during an expiration-swallow-expiration pattern (E-S-E). It is described that the exhalatory position of the larynx induces a slightly adducted arytenoid-vocal fold position affording a protective setpoint for further laryngeal closure. Moreover, the hyolaryngeal excursion observed during this expiratory phase contributes to the opening of the upper esophageal sphincter (UES). Hence, the occurrence of pathological RSP's (pathRSP) imply reduced airway protection, resulting in an increased risk for aspiration and aspiration pneumonia.

Previous studies confirm the presence of pathRSP in up to 60% of HNC-patients post (CC)RT. It can be hypothesized that swallowing therapy programs aiming to improve the RSP in patients with RAD, may significantly improve the patients' swallowing function. A recent non-randomized study by Martin-Harris and colleagues provided a first indication for the positive effect of treatment of pathRSP by means of visual feedback in a heterogeneous HNC-cohort. However, further research in training RSP, its retention and possible confounding factors is necessary to improve quality care in patients with RAD.

Who can participate?
Patients aged 18 years or older, with radiation associated dysphagia after head and neck cancer treatment

What does the study involve?
Patients will be randomized to one of two treatment arms, each following a different timeline. Irrespective of their group, all participants will receive the same intervention, namely 4 sessions of respiratory swallow therapy (RES-ST) in a period of two weeks. During these sessions, patients are learned to coordinate their RSP, receiving feedback of from respiratory inductance plethysmography (RIP) and their therapist. Group 1 starts immediately with RES-ST, following a two-week retention period. Group 2 initially serves as a control group during the first two weeks, receiving RES-ST in the last two weeks. To measure the effect and the retention of RES-ST, 3 videofluoroscopic swallowing examinations will take place before the intervention (group 1 and 2), after RES-ST (group 1), after the control period (group 2), after the retention period (group 1) and after RES-ST (group 2).

What are the possible benefits and risks of participating?
A key benefit of participation is an increased number of normal respiratory swallow patterns, which indicate a safer swallow function. There are no risks or side effects associated with participating in the study.

Where is the study run from?
Antwerp University Hospital (Belgium)

When is the study starting and how long is it expected to run for?
January 2024 to June 2028

Who is funding the study?
Kom Op Tegen Kanker (Belgium)

Who is the main contact?
Drs Charlotte Schellen, charlotte.schellen@uantwerpen.be

Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effect of respiratory swallowing therapy in patients with radiation associated dysphagia on swallowing function and quality of life

Acronym
RES-ST

Study objectives
RES-ST will improve the safety of the swallowing function and quality of life of patients with radiation associated dysphagia after head and neck cancer treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/10/2024, Ethics committee of Antwerp University Hospital (Drie Eikenstraat 655, Antwerp, 2650, Belgium; +32 (0)3 821 38 97; ethisch.comite@uza.be), ref: 6867

Study design
Single-centre interventional two-arm cross-over randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Dysphagia

Interventions
Patients will be randomized to one of two treatment arms, each following a different timeline. Irrespective of their group, all participants will receive the same intervention, namely 4 sessions of RES-ST in a period of two weeks. These sessions take place at the patient's home or nursery home and is supervised by one of the researchers. All sessions will consist of at least 100 (food bolus) swallows with the super-supraglottic swallow maneuver (SSGS). These swallows will gradually build up, varying in type of bolus (IDDSI levels) and volume (5-10-15 ml and spontaneous cup swallows). During the swallows, the respiratory inductance plethysmography (RIP) and the speech language therapist provide feedback on the respiratory swallow patterns used. Feedback will start at 100% for each new bolus type and will decrease systemically depending on the skill acquisition to avoid feedback dependency. Besides the 4 sessions, participants will practice daily on their own (two sets of 10 swallows) during the two-week intervention period.

Intervention Type

Behavioural

Primary outcome(s)
PAS (Penetration-Aspiration Scale) score at baseline and after RES-ST

Key secondary outcome(s))
Secondary outcome measures, measured at baseline (T0), two weeks after baseline (T1) and four weeks after baseline (T2):
1. Swallowing function, measured with the Modified Barium Swallow Impairment Profile (MBSImP) and the Dynamic Imaging Grade of Swallowing Toxicity (DIGEST).
2. Patient reported outcome with the Eating Assessment Tool (EAT-10).
3. Respiratory outcome measures: percentage of pathological respiratory swallow patterns and the percentage of normal respiratory swallow patterns.
4. Quality of life, based on the results of the Dysphagia Handicap Index (DHI), the M.d. Anderson Dysphagia Inventory (MDADI) and the Dutch version of the Performance Status Scale for Head and Neck Cancer (D-PSS-HN).

Tertiary/exploratory endpoint:
Data on the following confounders will be collected at baseline:
1. Patient characteristics: age, gender, duration of RAD, frailty (Clinical Frailty Scale), COPD-status (GOLD-criteria). COPD-stage will be determined at the pneumology department. The occurrence of (aspiration) pneumonias before, during and after RES-ST treatment.
2. Disease characteristics: tumor size (TNM-classification), HPV-status and feeding mode (enteral vs oral), gathered through medical records of the patient. The functional oral intake will be questioned by means of the Functional Oral Intake Scale (FOIS) and the Food Intake Level Scale (FILS). The clinical swallow function will be described with the Mann Assessment of Swallowing Ability Scale for Cancer patients (MASA-C).
3. Therapy characteristics: chemotherapy, fractionation, bilateral neck irradiation, duration, time post treatment, all gatherd through medical records of the patient.
Data on the following confounders will be collected after two weeks of RES-ST:
1. Attitudes about exercising, based on the results on the Attitudes On Exercise questionnaire
2. Level of patient activation, based on the results on American short form Patient Activation Measure (PAM-13)
3. Perceived effort during exercising, by doing an interview after each session of RES-ST
4. Degree of overall adherence, based on the completion of the four RES-ST sessions

Completion date
30/06/2028

Eligibility

Key inclusion criteria
1. Diagnosis of radiation-associated dysphagia following head and neck cancer. Based on a deviant result on the Penetration-Aspiration Scale (PAS score > 1) (Rosenbek et al., 1996)
2. ≥ 6 months post cancer treatment. Based on the knowledge that radiation toxicities are clinically classified into acute, subacute, or chronic. Early mucosal injuries (acute <3 months or subacute 3–6 months post irradiation) are attributed to cell death and subsequent inflammation; whereas late deeper tissue responses (chronic >6 months post irradiation) are attributed to damage to the vasculature and/or surrounding connective tissue. Often acute injuries are transient and resolve within a few months after treatment. In order to study the effect of this specific treatment, it’s important to include only patients without possible spontaneous

recovery as described in the acute phase <6 months (King et al., 2016)
3. Previous swallowing rehabilitation including strength training is allowed, but not simultaneously

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. Severe frailty: ≥level 7 @ the Clinical Frailty Scale (Rockwood et al., 2005)
2. Cognitive or language impairments interfering with the therapy/assessments within RES-ST
3. Major surgery in the head and neck

Date of first enrolment
07/03/2025

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Belgium

Study participating centre
Antwerp University Hospital
Drie Eikenstraat 655
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Study participating centre

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Sponsor information

Organisation
Antwerp University Hospital

ROR
https://ror.org/01hwamj44

Funder(s)

Funder type
Charity

Funder Name
Kom op tegen Kanker

Alternative Name(s)
Fight Cancer, komop_tegenkanker

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during and/or analyses during the current study will be stored in a non-publicly available repository (Redcap)

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes