

Tongue strengthening exercises in head and neck cancer patients: does level of resistance matter?

Submission date 12/02/2015	Recruitment status Recruiting	☐ Prospectively registered ☒ Protocol
Registration date 19/02/2015	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 27/10/2020	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Reduced tongue strength (TS) is an important contributing factor to early and late dysphagia (swallowing difficulties) in head and neck cancer (HNC) patients previously treated with chemoradiotherapy (CRT). The evidence is growing that tongue-strengthening exercises (TSE) can improve TS and swallowing function in both healthy and dysphagic subjects. However, little is known about the impact of specific features of an exercise protocol for TS on strength and/or swallowing function). Previous research in sports medicine and physical rehabilitation shows that degree of exercise load is an influential factor for increasing muscle strength in the limb skeletal muscles. Since the tongue is considered a muscular hydrostat (a structure that helps manipulate food), it remains to be proven if the same concepts will apply. This study investigates the effect of 3 TSE protocols with different degrees of exercise load on TS and swallowing.

Who can participate?

Adult head and neck cancer patients previously treated with chemoradiotherapy and suffering from chronic dysphagia.

What does the study involve?

Participants will be randomly assigned to a training schedule of 60, 80, or 100% of their maximal TS respectively. They will be treated during 8 weeks, 3 times a week, executing 120 repetitions of the assigned exercise once per training day. Exercise load is progressively adjusted every two weeks. Patients are evaluated before, during and after treatment by means of TS measurements, fiber optic endoscopic evaluation of swallowing (FEES) and quality of life questionnaires.

What are the possible benefits and risks of participating?

A possible benefit is the increase of tongue strength to some degree, in some participants. There are no risks for patients participating in this 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?
March 2014 to December 2027

Who is funding the study?
Antwerp University Hospital and Federal Cancer Plan Belgium

Who is the main contact?
Prof Gwen Van Nuffelen

Contact information

Type(s)
Scientific

Contact name
Dr Gwen Van Nuffelen

Contact details
Wilrijkstraat 10
Edegem (Antwerp)
Belgium
2650

Additional identifiers

Protocol serial number
NKR_2014_01

Study information

Scientific Title
Effect of intensive tongue strength therapy on anterior and posterior tongue strength, dysphagia and dysphagia related quality of life.

Study objectives

1. Tongue strengthening exercises improve tongue strength in head and neck cancer patients.
2. Tongue strengthening exercises improve functional swallowing in this population.
3. Tongue strengthening exercises improve swallowing related quality of life.
4. The effect of tongue strengthening exercises depend upon the level of resistance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Antwerp University Hospital and University of Antwerp, Belgium. Chair: Prof. Dr. Patrick Cras. ref 14/24/253, B300201421549

Primary study design
Interventional

Study design

Single-centre interventional randomized controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patients with dysphagia following head and neck cancer or neurodegenerative diseases.

Interventions

At enrollment, 45 head and neck cancer patients, whose dysphagia is primarily related to reduced tongue strength, are randomly assigned to a training schedule of 100% (group 1), 80% (group 2), or 60% (group 3) of their maximal TS respectively. Patients will be treated during 8 weeks, 3 times a week, executing once per training day 120 repetitions of the assigned exercise. Exercise load is progressively adjusted every two weeks. Patients are evaluated before, during and after treatment by means of TS measurements, fiberoptic endoscopic evaluation of swallowing (FEES) and quality of life questionnaires.

Intervention Type

Behavioural

Primary outcome(s)

1. Tongue strength measurements: Maximum Isometric Pressures (expressed as kPa) anterior and posterior.

The primary measures are evaluated prior to (max 1 week in advance), during (after 4 weeks of therapy), after 8 weeks of therapy and 4 and 8 weeks post treatment.

Key secondary outcome(s)

1. Swallowing function: the swallowing function will be evaluated using a comprehensive fiber optic endoscopic evaluation of swallowing (FEES) examination, the - Mann Assessment of Swallowing Ability-Cancer (MASA-C), the Functional Oral Intake Scale (FOIS), and a self-evaluation. For the latter a 100 mm visual analogue scale is used with the ends defined as 'I can't swallow' (0) and 'I don't have any swallowing difficulties' (100) respectively. Both the FEES and MASA-C are conducted with 4 different bolus types: 5 and 10 ml of thin liquid, and 5 and 10 ml of yoghurt. Each bolus type is administered 3 times. Outcome measures for FEES are the Penetration-Aspiration-Scale, the Carnaby- Video Fluoroscopic Examination (C-VFE) scales for dysphagia and aspiration, the Pooling-score and the Boston Residue and Clearance Scale (BRACS).

2. Quality of Life: swallowing-related quality of life will be surveyed by means of the Dutch Swallowing Quality-of-Life Questionnaire (DSWAL-QoL) and the Dysphagia Handicap Index. The secondary outcome measures are evaluated prior to (max 1 week in advance), during (after 4 weeks of therapy), after 8 weeks of therapy and 4 and 8 weeks post treatment.

Completion date

31/12/2027

Eligibility

Key inclusion criteria

1. Head and neck cancer patients previously treated with chemoradiotherapy
2. Men and women older than 18, without cognitive, language, motor, hearing or visual deficits that could interfere with the correct execution of the training.
3. Chronic dysphagia (i.e. present for at least 1 month and no earlier than 6 months after the last day of radiation treatment), primarily related to reduced tongue strength
4. Score 1 or higher for the BRACS-items 'base of tongue' and/or 'valleculae' at baseline judged by an experienced clinician

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. History of major oral or head and neck surgery and neurological disorders with an impact on oral function and/or swallowing (amongst others stroke, traumatic brain injury, Parkinson's disease, Amyotrophic Lateral Sclerosis).
2. Concurrent oral motor exercises or swallowing maneuvers to improve swallowing are not allowed during the study period.

Date of first enrolment

01/05/2014

Date of final enrolment

01/12/2027

Locations**Countries of recruitment**

Belgium

Study participating centre

Antwerp University Hospital

Edegem

Belgium

-

Sponsor information

Organisation

Antwerp University Hospital (Belgium)

ROR

<https://ror.org/01hwamj44>

Funder(s)

Funder type

Government

Funder Name

Federal Cancer Plan Belgium

Funder Name

Antwerp University Hospital (Belgium)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/09/2015		Yes	No