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

Submission date
12/02/2015

Recruitment status
Recruiting

Registration date
19/02/2015

Overall study status
Ongoing

Last Edited
27/10/2020

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/03/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45 (15 per group)

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)

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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Publication of the study protocol
publication of the data at completion of the study
Presentation of the data at at least 2 international conferences including the Dysphagia Research society Meeting

Intention to publish date
31/12/2017

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