ISRCTN47855281 https://doi.org/10.1186/ISRCTN47855281

Clinical practices in head and neck cancer: the role of the speech and language pathologist in assessment and management of swallowing disorders in patients treated with radiotherapy in Flanders

Submission date
27/07/2022

Recruitment status
No longer recruiting

Registration date
06/10/2023

Overall study status
Completed

Last Edited
28/08/2024

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Fifty to 60% of the patients who are treated with radiotherapy (RT) or (chemo)radiotherapy (CRT) for head and neck cancer (HNC) develop swallowing disorders. Swallowing disorders can occur as an acute side effect during treatment, but can also persist for months to years after RT treatment. Literature shows that quality of life (QoL) in HNC patients treated with CRT improves significantly when patients are referred to a speech language pathologist (SLP) for education and assessment prior to treatment. Furthermore, several studies already demonstrated the positive effects of preventative strengthening exercises for the swallowing musculature, on muscle condition and swallowing function.
However, to the researchers' knowledge, there is no gold standard in Flanders for the assessment, counseling or (preventive) treatment of swallowing disorders in HNC patients and no data are available on the effective implementation of these aspects or on the role of the SLP within the HNC team. Therefore, the aim of this study is to assess the accessibility and provision of swallowing assessment, counseling and treatment by an SLP, before, during and after CRT for HNC patients in Flanders by means of an online survey.

Who can participate?
Radiation oncologists treating HNC patients in 11 radiotherapy centers in Flanders

What does the study involve?
This survey is sent out via a web-based application in May 2022 and a reminder to complete the questionnaire is sent out after 3 and 5 weeks.

What are the possible benefits and risks of participating?
There are no known risks with participation. The possible benefit is increased insight into dysphagia management in head and neck cancer patients in Flanders.

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

When is the study starting and how long is it expected to run for?
February 2022 to July 2022

Who is funding the study?
Kom op tegen Kanker (Belgium)

Who is the main contact?
1. Prof. Dr Fréderic Duprez, frederic.duprez@uzgent.be
2. Margot Baudelet, margot.baudelet@Ugent.be

Contact information

Type(s)
Principal investigator

Contact name
Prof Fréderic Duprez

Contact details
University Hospital Ghent
Corneel Heymanslaan 10
Ghent
Belgium
9000
+32 (0)3 821 30 00
frederic.duprez@uzgent.be

Type(s)
Scientific

Contact name
Ms Margot Baudelet

ORCID ID
https://orcid.org/0000-0003-0431-5854

Contact details
University Hospital Ghent
Corneel Heymanslaan 10
Ghent
Belgium
9000
+32 (0)93320872
margot.baudelet@Ugent.be

Additional identifiers

Protocol serial number
ONZ-2022-0005

Study information

Scientific Title
Clinical practices in head and neck cancer: the role of the speech and language pathologist in assessment and management of dysphagia in patients treated with radiotherapy in Flanders

Study objectives
Literature indicates that, despite increased attention, accessibility to early dysphagia management in head and neck cancer (HNC) patients often remains a problem. Although an increasing number of studies point to the fact that a speech language pathologist (SLP) plays an important role in the multidisciplinary team of HNC patients, there is no gold standard in Flanders for the assessment, counseling or (preventive) treatment of dysphagia in HNC patients. Consequently, to the researchers' knowledge, no data are available on the effective implementation of these aspects or on the role of the SLP within the HNC team. Therefore, the aim of this study is to assess the accessibility and provision of swallowing/dysphagia assessment, counseling and treatment by an SLP, before, during and after (chemo)radiotherapy (CRT) for HNC patients in Flanders by means of an online survey.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/02/2022, University Hospital Ghent Ethics Committee (C. Heymanslaan 10, 9000 Ghent, Belgium; +32 (0)9 332 33 36; ethisch.comite@uzgent.be), ref: ONZ-2022-0005

Primary study design
Observational

Study design
Prospective observational study

Study type(s)
Other

Health condition(s) or problem(s) studied
Dysphagia management in head and neck cancer patients treated with radiotherapy in Flanders

Interventions
The aim of this survey study is to assess the accessibility and provision of swallowing/dysphagia assessment, counseling and treatment by an SLP, before, during and after CRT for HNC patients in Flanders by means of an online survey. This online survey is sent to all RT centers in Flanders treating HNC patients via REDCap (Research Electronic Data Capture) electronic data capture tools hosted at Ghent University Hospital).

Intervention Type
Behavioural

Primary outcome(s)
Availability of dysphagia management and the role of the SLP in HNC patients, measured by means of a web-based survey sent to radiation oncologists in Flanders at a single timepoint

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. Radiation oncologists
2. Working in Flemish hospitals with a radiotherapy department
3. Responsible for the treatment of HNC patients

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
10

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
20/05/2022

Date of final enrolment
20/06/2022

Locations

Countries of recruitment
Belgium

Study participating centre

University Hospital Ghent
Corneel Heymanslaan 10
Ghent
Belgium
9000

Sponsor information

Organisation
Ghent University Hospital

ROR
https://ror.org/00xmkp704

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 datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. All data will be stored in REDCap, a secure web application for building and managing online surveys and databases (https://www.project-redcap.org/). The data will be available for all participating study investigators until the end of the study. All data will be anonymised and participant details will be encoded.

IPD sharing plan summary

Stored in non-publicly available repository