

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/10/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/08/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 Frédéric Duprez, frederic.duprez@uzgent.be
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Contact information

Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Study design

Prospective observational study

Primary study design

Observational

Secondary study design

Prospective observational study

Study setting(s)

Hospital

Study type(s)

Other

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

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 measure

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

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

07/02/2022

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

Age group

Adult

Sex

Both

Target number of participants

11

Total final enrolment

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

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9000

Sponsor information

Organisation

Ghent University Hospital

Sponsor details

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info@uzgent.be

Sponsor type

Hospital/treatment centre

Website

<https://www.uza.be>

ROR

<https://ror.org/00xmkp704>

Funder(s)

Funder type

Charity

Funder Name

Kom op tegen Kanker

Alternative Name(s)

Fight Cancer

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Belgium

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly 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