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Can we use ultrasound to assess the structure and size of important speech and swallowing muscles before and after radiotherapy ?

Submission date 03/03/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 06/03/2025	**Overall study status** Ongoing	
Last Edited 06/03/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Radiotherapy is regularly used to cure and treat head and neck cancer. It can lead to changes in the structure and function of important muscles used in speech and swallowing, such as those in the tongue, neck, and jaw. Changes start during radiotherapy and can become worse over time, even after treatment finishes. We do not understand exactly when or how these changes happen, or how to treat them. Patients tell us side effects of radiotherapy can be very difficult to live with. This research aims to establish if ultrasound will be helpful in assessing the size and structure of the muscles involved in speech and swallowing in head and neck cancer patients before and after radiotherapy treatment.

The outcomes will be:
1. Assess whether ultrasound is helpful for assessing speech and swallowing muscles in head and neck cancer.
2. Find out if participants find ultrasound an acceptable assessment
3. Compare ultrasound findings of the 20 head and neck cancer patients with patient reported outcomes.
4. Complete engagement activities with patients and the public about their thoughts regarding ultrasound to guide the research. This will include focus group discussions, interviews and trying out ultrasound equipment.

Who can participate?
This will be a small pilot study of approximately 20 patients.
Patients will have a diagnosis of squamous cell cancer of the head and neck area.
Their treatment will be radiotherapy or chemotherapy plus radiotherapy with the aim of curing their cancer

What does the study involve?
The study involves the participants having an ultrasound before they start radiotherapy, and

between 3-6 months after they have finished. They will also fill out two questionnaires about their swallowing and speech symptoms, and another questionnaire about the ultrasound. This will help understand if ultrasound is acceptable to participants.

What are the possible benefits and risks of participating?
There are no direct benefits to participants. There are no risks to participants although the ultrasound is extra time spent in clinic.

The expected benefits of the overall research are:
1. Improved understanding of the effects of radiotherapy on the structure and possible link to for function of speech and swallowing muscles in head and neck cancer patients
2. Potential for early identification of muscle changes using ultrasound imaging. This will enable targeted rehabilitation exercises for patients that may slow down any deterioration in how the muscles are working.
3. Understanding what patients and the public think about the introduction of ultrasound as part of their treatment.

Where is the study run from?
The study is run from Charing Cross Hospital (UK)

When is the study starting and how long will it run for?
September 2024 to December 2025

Who is funding the study:
Imperial College London Seedfund Grant, and an NIHR Senior Clinical and Practitioner Research Award (UK)

Who is the main contact?
Dr Gemma Clunie, gemmaclunie@nhs.net

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
342478

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EDGE 173802

Study information

Scientific Title
An investigation of the feasibility, reliability and acceptability of using of ultrasound to assess muscle echogenicity and size in key speech and swallowing tissues before and after radiotherapy in a head and neck cancer population

Acronym
QMUS-HNC-RT

Study objectives
It is feasible, reliable, and acceptable to use ultrasound assessment to assess muscle echogenicity and size in a pre- and post-radiotherapy head and neck cancer population.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/12/2024, West Midlands - Solihull (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 207 104 8124; solihull.rec@hra.nhs.uk), ref: 24/WM/0224

Study design
Feasibility reliability and acceptability study to use an ultrasound assessment protocol in clinical practice with a head and neck cancer population with an embedded pilot observational study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)

Other, Quality of life

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Squamous cell carcinoma of tongue, tongue base, tonsil, oropharynx, hypopharynx or larynx, radical radiotherapy or chemoradiotherapy as primary curative treatment plan.

Interventions
Participants will fill in questionnaires and have ultrasound assessment at baseline and between 3 and 6 months post treatment.

Participants will be enrolled in the study for approximately 6 months, depending on the timing of the post-treatment ultrasound scan which will be arranged at a convenient date and time to the participant.

Intervention Type
Other

Primary outcome measure
Feasibility outcome measures:
1. Visibility of each muscle is measured using a three-point scale of visibility (clear, questionable, not visible) at baseline and between 3 and 6 months post treatment
2. Echogenicity is measured using greyscale analysis at baseline and between 3 and 6 months post treatment
3. Muscle thickness is measured using electronic callipers at baseline and between 3 and 6 months post treatment
4. Cross-sectional area is measured using continuous trace calipers at baseline and between 3 and 6 months post treatment
5. Inter-rater measurement reliability of thickness, cross-sectional area, and echogenicity is measured using intra-class correlation coefficient (ICC) at baseline and between 3 and 6 months post treatment
6. Intra-rater measurement reliability of thickness, cross-sectional area, and echogenicity is measured using Cronbach's alpha at baseline and between 3 and 6 months post treatment
7. Acceptability of US to patients is measured using survey responses and a visual analogue scale at baseline and between 3 and 6 months post treatment

Secondary outcome measures
1. Ultrasound data will be collected prior to radiotherapy (baseline), and following radiotherapy (at least 3 months post) - the images will be used to assess the parameters described below:
1.1. Visibility data will be described using a three-point scale of visibility (clear, questionable, not visible)
1.2. Echogenicity (gray scale) of a defined region of interest for each muscle will be measured using specialist software, this will generate a numeric value between 0 and 255
1.3. Muscle thickness will be calculated by electronic callipers positioned at standard locations; cross-sectional area will be calculated using continuous trace calipers to outline the muscles of interest which will automatically generate a cross-sectional area.

2. Patient Reported Outcome Measures
2.1. Experience of swallowing symptoms measured using the MD Anderson Dysphagia Index

(MDADI) at baseline and following radiotherapy (at least 3 months post)
2.2. Experience of speech symptoms Speech Handicap Index (SHI) measured at baseline and following radiotherapy (at least 3 months post)

3. Clinical Reported Outcome Measures
3.1. Clinician rating of swallowing and speech performance will be measured by the Performance Status Scale Head and Neck (PSS-H&N) at baseline and following radiotherapy (at least 3 months post)
3.2. Clinician rating of diet and fluid level and intake will be measured by the Functional Oral Intake Scale (FOIS) at baseline and following radiotherapy (at least 3 months post)
3.3. Clinican rating of diet and fluid description will be measured by the International Dysphagia Diet Standardisation Initiative (IDDSI) diet and fluids level at baseline and following radiotherapy (at least 3 months post)

4. Acceptability
4.1. An online questionnaire including visual analogue score (VAS) will be used to assess acceptability of the ultrasound at baseline and following radiotherapy.

Overall study start date
09/09/2024

Completion date
06/12/2025

Eligibility

Key inclusion criteria
1. Over 18 years
2. Diagnosis of squamous cell carcinoma of tongue, tongue base, tonsil, oropharynx, hypopharynx or larynx
3. Radical radiotherapy/chemoradiotherapy as primary curative treatment plan
4. Able to give written consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria

1. Under 18 years
2. Other primary carcinoma site
3. Surgery as primary treatment plan
4. Unable to give written consent
5. Unable to complete patient reported outcome measures due to cognitive impairment

Date of first enrolment
07/03/2025

Date of final enrolment
06/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College Healthcare NHS Trust
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Sponsor information

Organisation
Imperial College Healthcare NHS Trust

Sponsor details
Research Governance and Integrity Team
Imperial College London and Imperial College Healthcare NHS Trust
Room 215, Level 2, Medical School Building
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Sponsor type

Hospital/treatment centre

Website
http://www.imperial.nhs.uk/

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
University/education

Funder Name
Imperial College London

Alternative Name(s)
Imperial College of Science, Technology and Medicine, Imperial College London, UK, Imperial College London, London, England, Imperial College London in United Kingdom, imperialcollege, ICL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Final study report will be produced summarising the data collected. All data used will be anonymised. This will be sent out to patient charities, forums and social media and published on the Imperial College website. We will ask each participant if they would like to receive the report. These will be worded using lay terminology and supported by the patient advisory group. The information will also be available on the chief investigator's website https://profiles.imperial.ac.uk/g.clunie
The work will be submitted to conferences such as the UK Swallow Research Group (UK SRG), Dysphagia Research Society (DRS) and the British Association of Head and Neck Oncologists (BAHNO) as well as peer reviewed journals. The results of the study will also be reported internally to the Speech and Language Therapy and Head and Neck Cancer multidisciplinary teams at Imperial College Healthcare NHS Trust

Intention to publish date
01/03/2027

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study will be available upon request from Dr Gemma Clunie gemmaclunie@nhs.net

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.3	05/11/2024	06/03/2025	No	Yes
Protocol file	version 1.4	26/11/2024	06/03/2025	No	No