

# Development of a cohort to analyse outcomes in cancer of the voicebox (laryngeal cancer)

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<b>Registration date</b> 12/08/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/01/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Cancer of the voice box (laryngeal cancer) is one of the most common cancers of the head and neck. Patients are often quite severely affected. The disease and its treatment affect a patient's swallow, voice, appearance, and wellbeing. At the moment, there are various treatments available including radiotherapy, chemotherapy, laser surgery or total laryngectomy (complete removal of the voice box). Any of these treatments can lead to the insertion of a permanent tube in the neck for breathing (tracheostomy) or a feeding tube. Although there has been research performed on which treatments are best for patients with laryngeal cancer, we have not made any significant progress in the treatment of this disease for around 30 years. There is a huge variation in how patients respond to treatment; some patients respond very well, whereas others have a lot of severe side effects with a subsequent impact on their quality of life. It is impossible to predict which patients will do well or badly on which treatment meaning that there is huge variation around the country in the treatments offered. Ultimately, we need to be able to predict how a patient with laryngeal cancer is likely to respond to treatment. If we were able to do this, this would allow us to make progress in the treatment of this disease, inform our discussions with patients, and allow us to develop new ways of tailoring treatments to individual patients.

### Who can participate?

Adults with laryngeal cancer

### What does the study involve?

The aim of the study is to establish an "enhanced cohort study" – that is, a large group of patients with newly diagnosed laryngeal cancer, from whom data and samples will be collected, and who will be followed through treatment and beyond. Details about the patient's cancer (such as their swallowing function and medical images made using computerized tomography [CT]) will be compared to their treatment outcome. This cohort could then be used as a foundation for future research in this disease, including working out which treatment will be best for which patient – this is called personalised medicine.

We will set up our enhanced cohort in eight large head and neck centres. All of these see a lot of patients with laryngeal cancer and are committed to making this project work successfully. Once

the cohort is set up, tissue biopsies will be taken from the patients' cancers and diagnosis scans will be assessed. Analyses of these samples will be conducted to compare the molecular and genetic detail as well as the data generated from the CT scan with the response of the patient and cancer to the treatment. In this way, we will be able to begin the analysis of disease biomarkers which, in turn, may lead us to help with the development of new and novel therapies.

What are the possible benefits and risks of participating?

There are no known benefits and risks to participants as the study is designed to collect routine data

Where is the study run from?

Freeman Hospital (UK)

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

July 2022 to June 2027

Who is funding the study?

1. Medical Research Council (UK)

2. National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?

Mr David Hamilton

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## Contact information

**Type(s)**

Public

**Contact name**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

## **Integrated Research Application System (IRAS)**

306921

## **ClinicalTrials.gov (NCT)**

Nil known

## **Protocol serial number**

IRAS 306921, CPMS 52643

# **Study information**

## **Scientific Title**

Precision medicine in laryngeal cancer: development of a laryngeal cancer cohort

## **Acronym**

LARCH

## **Study objectives**

1. How do survival and quality of life outcomes compare between surgery and (chemo) radiotherapy in early and advanced laryngeal cancer?
2. How do the presenting features of laryngeal cancer influence oncological, functional and quality-of-life outcomes?

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 31/05/2022, London - Surrey Borders Research Ethics Committee, (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)20 7104 8057; surreyboundaries.rec@hra.nhs.uk), ref: 22/PR/0406

## **Study design**

Multicentre observational study

## **Primary study design**

Observational

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Laryngeal cancer

## **Interventions**

This study is the first enhanced laryngeal cancer disease cohort. We aim to deliver a cross-sectional study of 150 patients. Patient, tumour, quality-of-life and laryngeal functional data will be collected at baseline, 6, 12 and 24 months. Multiple logistic regression analyses will be used to:

1. Identify patient-related, clinical- and health service-related (e.g. institution) factors associated with receipt of surgical versus non-surgical treatment

2. Quantify locoregional control and identify factors associated with control overall and by treatment modality
  3. Identify factors associated with quality of life overall and by treatment modality
- Epidemiological approaches to support treatment comparisons within observational datasets (e.g. propensity scores, instrumental variable analysis) will be used

### **Intervention Type**

Other

### **Primary outcome(s)**

1. Tumour status measured by clinical assessment at 6, 12 and 24 months
2. Disease-specific survival measured using disease status at 6, 12 and 24 months
3. Overall survival measured at 6, 12 and 24 months

### **Key secondary outcome(s)**

1. Laryngeal function measured using GRBAS (grade, roughness, breathiness, asthenia, strain) scale, maximum phonation time, Voice Handicap Index (VHI-10), MD Anderson Dysphagia Inventory (MDADI), Performance Status Scale for Head & Neck Cancer Patients (PSS-HN), Videofluoroscopic Swallow Study (VFSS) and Flexible Endoscopic Evaluation of Swallowing (FEES) at baseline, 6, 12 and 24 months
2. Quality of life measured using EORTC Core Quality of Life questionnaire (EORTC QLQ-C30) and the EORTC Head and Neck Cancer Module (EORTC HN35) at baseline, 6, 12 and 24 months
3. Swallow measured using MDADI, PSS-HN, VFSS and FEES at baseline, 6, 12 and 24 months
4. Voice outcome measured using GRBAS, maximum phonation time, VHI-10 at baseline, 6, 12 and 24 months

### **Completion date**

07/06/2027

## **Eligibility**

### **Key inclusion criteria**

1. Confirmed new diagnosis of laryngeal cancer (Group 2)
2. Suspected but unconfirmed laryngeal cancer (Group 1)
3. Aged 18 years old and over
4. Capacity to consent
5. Ability to understand written and spoken English

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Aged 17 years old and younger
2. No capacity to consent
3. Recurrence or second head and neck primary cancer
4. Not able to adequately understand written or spoken English

**Date of first enrolment**

25/07/2022

**Date of final enrolment**

07/06/2025

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Freeman Hospital**

Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Sponsor information****Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust

**ROR**

<https://ror.org/05p40t847>

**Funder(s)****Funder type**

Research council

**Funder Name**

Medical Research Council

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**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

**Individual participant data (IPD) sharing plan**

1. Subject to review and approval from the Trial Management Group and development of a study-specific data management plan and ethical approval, data collected will be made available to other researchers
2. The committee will develop guidelines and processes (standard operating procedures) to define:
  - 2.1. How researchers/individuals/ groups/organisations can bring studies for adoption
  - 2.2. How multi-disciplinary (including public/patient) peer review of applications will operate
  - 2.3. The basis on which proposals will be prioritised
  - 2.4. Data sharing and discoverability requirements that applicants must agree to fulfill
3. Consent is obtained from participants for anonymised data collection as clinical information about tumour status, co-morbidities, quality of life and functional data will be stored in the

REDCap repository; the process for requesting access is in the trial protocol, and a standard operating procedure will be made available at a later date

**IPD sharing plan summary**

Stored in non-publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		13/10/2023	16/01/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version 3	27/05/2022	01/07/2022	No	Yes
<a href="#">Protocol file</a>	version 3	27/05/2022	01/07/2022	No	Yes