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

Submission date
24/06/2022

Recruitment status
No longer recruiting

Registration date
12/08/2022

Overall study status
Ongoing

Last Edited
16/01/2023

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
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
david.hamilton@ncl.ac.uk

Contact information

Type(s)
Public

Contact name
Mr David Hamilton

ORCID ID
http://orcid.org/0000-0002-9653-6453

Contact details
ENT Department
Level 3
Freeman Hospital
Newcastle upon Tyne
United Kingdom
NE7 7DN
+44 (0)191 2137625
david.hamilton@ncl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
306921

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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; surreyborders.rec@hra.nhs.uk), ref: 22/PR/0406

Study design
Multicentre observational study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See trial outputs table

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 measure
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

Secondary outcome measures
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

Overall study start date
31/05/2022

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

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
England

United Kingdom

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

Sponsor details
Freeman Hospital
High Heaton
Newcastle upon Tyne
England
United Kingdom
NE7 7DN
+44 (0)191 2137625
nuth.nuthsponsorship@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

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, 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

Publication and dissemination plan
1. Data from the study will be disseminated to participating centres within the study via the Trust's websites
2. Lay summaries will be prepared, posted on the study website and disseminated through websites of individual participating sites and charities
3. Digital tools for dissemination of research findings will be developed and information disseminated to individuals requesting this
4. For academic and clinical dissemination, chief investigator will take responsibility to submit data for publication in high-impact international peer-reviewed journals and present to scientific meetings
5. Access to the anonymised LARCH dataset by other researchers will be publicised and promoted. The data sharing policy pertaining to this dataset will be made available to researchers
6. Additional dissemination for benefit of patients and the public will be developed including the use of digital media.
7. Recipients working in academic institutions are expected to submit their results to a peer-reviewed journal as soon as possible- ideally with open access. Manuscripts should be sent to the custodian prior to submission to establish compliance with the terms of acceptance. The custodian will undertake to keep the contents of submitted manuscripts confidential until publication. If the researchers wish to have this period extended to protect intellectual property (IP), they should discuss this with the custodian.
8. Publications should also be deposited in the UK PubMed Central database within three months of publication
9. Details of any publications resulting from the use of the samples should be forwarded to the custodian immediately after they become accessible
10. Details of all publications arising from the use of samples in the bank will be held in a database accessible from the website. Recipients should aim to publish the results of all studies, including negative results unless this is not possible because of the need to protect IP. If it is not possible to publish negative findings, the manuscript should be submitted to the custodian for inclusion in the collection.
11. Any publication or presentation using data or samples from the collection should include an acknowledgment using the text: "Samples used in this research were obtained from the LARCH Biobank"

Intention to publish date
07/02/2028

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?
Participant information sheet	version 3	27/05/2022	01/07/2022	No	Yes
Protocol file	version 3	27/05/2022	01/07/2022	No	Yes
Protocol article		13/10/2023	16/01/2023	Yes	No
HRA research summary			28/06/2023	No	No