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Dose escalated intensity modulated radiotherapy versus standard dose intensity modulated radiotherapy in laryngeal and hypopharyngeal cancer patients

Submission date 17/01/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 31/03/2011	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 24/03/2022	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-study-looking-increasing-dose-radiotherapy-treat-cancer-voice-box-or-lower-part-of-the-throat-art-deco

Study website
http://www.icr.ac.uk/research/research_sections/clinical_trials/trials_by_disease/head_and_neck/index.shtml

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ICR-CTSU/2009/10022

Study information

Scientific Title
A randomised multicentre accelerated radiotherapy study of dose escalated intensity modulated radiotherapy versus standard dose intensity modulated radiotherapy in patients receiving treatment for locally advanced laryngeal and hypopharyngeal cancers

Acronym
ART-DECO

Study objectives
To determine the potential of dose escalated intensity modulated radiotherapy (IMRT) to improve locoregional failure free rate (LRFFR) and laryngeal preservation in patients with locally advanced laryngeal and hypopharyngeal cancers, without increasing the incidence of severe acute and late toxicities to unacceptable levels.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central London Research Ethics Committee (REC) 4 approved on 18/10/2010 (ref: 10/H0715/48)

Study design
Parallel group phase III multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Locally advanced squamous cell cancers of the larynx or hypopharynx

Interventions
The dose escalated IMRT (experimental) treatment group will receive 67.2 Gy in 28 fractions (2.4 Gy per fraction) to the involved site and nodal groups and 56 Gy in 28 fractions (2.0 Gy per fraction) to nodal areas at risk of harbouring microscopic disease.

The standard dose IMRT (standard) treatment group will receive 65 Gy in 30 fractions (2.167 Gy per fraction) to the involved site and nodal groups and 54 Gy in 30 fractions (1.8 Gy per fraction) to nodal areas at risk of harbouring microscopic disease.

All patients will receive concomitant cisplatin 100 mg/m2 on day 1 and day 29 of the radiotherapy schedule however within the context of this trial, chemotherapy is not an investigational medicinal product.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Locoregional failure free rate (LRFFR).

Measured at 1, 2, 3, 4 and 8 weeks post-treatment and at 3, 6, 12, 18 and 24 months post treatment. Patients will then be followed up annually up to 5 years.

Secondary outcome measures
1. Laryngo-oesophageal dysfunction free rate
2. Overall survival (time from randomisation to death)
3. Acute and late toxicities following chemoradiation
4. Characteristics of patients who proceed to salvage neck dissection
5. Characteristics of patients who fail organ preservation
All of the above will be measured at 1, 2, 3, 4 and 8 weeks post-treatment and at 3, 6, 12, 18 and 24 months post treatment. Patients will then be followed up annually up to 5 years.
6. Patient assessed quality of life, measured using questionnaires administered at baseline, end of radiotherpay treatment, 6 months, 1 year and then annually to 5 years post-treatment

Overall study start date
01/02/2011

Completion date
01/12/2020

Eligibility

Key inclusion criteria
1. Aged 16 years or above, either sex
2. Histologically confirmed squamous cell cancer of the larynx or hypopharynx

3. Chemo-radiotherapy is the investigators treatment of choice. Induction chemotherapy is permitted.
4. Locally advanced squamous cell cancer of the larynx or hypopharynx i.e. stage III or IV a/b disease
5. World Health Organization (WHO) performance status of 0 or 1
6. Creatinine clearance of greater than 50 ml/min
7. Must be suitable to attend long term follow-up. All patients participating in the QoL study must have adequate cognitive ability to complete the QoL questionnaires.
8. Written informed consent

Patients may undergo surgical biopsy or non-radical surgery prior to study entry.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
354

Total final enrolment
276

Key exclusion criteria
1. Previous radiotherapy to the head and neck region
2. Clinical evidence of metastatic disease (Stage IVc)
3. Previous malignancy except non-melanoma skin cancer and early stage cancer in remission for at least 5 years following treatment
4. Previous or concurrent illness, which in the investigator's opinion would interfere with completion of therapy
5. Pre-existing previous speech or swallowing problems unrelated to the diagnosis of cancer
6. Large primary tumour, where organ preservation is unrealistic

Date of first enrolment
01/02/2011

Date of final enrolment
20/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Head and Neck Unit
London
United Kingdom
SW3 6JJ

Sponsor information

Organisation
Royal Marsden NHS Foundation Trust (UK)

Sponsor details
Fulham Road
London
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United Kingdom
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Sponsor type
Hospital/treatment centre

Website
http://www.royalmarsden.nhs.uk/home

ROR
https://ror.org/0008wzh48

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: CRUK/10/018)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/07/2021	14/07/2021	Yes	No
Plain English results		10/03/2022	24/03/2022	No	Yes