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EaStER: Early Stage glottic laryngeal cancer: Endoscopic excision or Radiotherapy? - a feasibility study

Submission date 10/05/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/06/2004	**Overall study status** Completed	
Last Edited 19/11/2015	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-radiotherapy-or-endoscopic-surgery-for-early-stage-cancer-of-the-glottis

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00334997

Secondary identifying numbers

N/A

Study information

Scientific Title
EaStER: Early Stage glottic laryngeal cancer: Endoscopic excision or Radiotherapy? - a feasibility study

Acronym
EaStER

Study objectives
The EaStER study applies only to patients with glottic cancer. This feasibility study is being carried out to determine whether it will be possible to conduct a large phase III trial to evaluate the outcome of patients treated with either endoscopic excision or standard radiotherapy. Outcome will be measured in terms of clinical outcome, voice quality, and quality of life. An economic assessment will also be carried out to determine the relative cost of each type of treatment to both patients and the NHS. Five centres are currently participating in this study. Data will be collected on the number of eligible patients approached, the number who agree to be registered into the voice/quality of life research, and the number who agree to be randomised for treatment. Patients who agree to take part in an associated qualitative research programme will also provide valuable data on patients' views on randomisation. The results of the feasibility study will determine whether it will be possible to recruit the required number of patients into an identical main trial within the UK.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
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
Early stage glottic cancer

Interventions
Endoscopic excision or standard radiotherapy

Intervention Type
Mixed

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2005

Completion date
31/07/2006

Eligibility

Key inclusion criteria
1. Histologically confirmed squamous cell carcinoma of the glottic larynx, including tumours at the anterior commisure
2. Stage Tis, T1, T2a, N0, M0
3. Anatomy of airways suitable for endoscopic excision
4. Fit to receive radical treatment as either radiotherapy or endoscopic excision
5. Age 18 years or greater
6. Willing to participate in a recruitment appointment
7. Willing to complete voice and quality of life questionnaires
8. Available for follow up within the UK

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria

1. Any clinical or radiological sign of nodal involvement
2. Any evidence of clinical metastases
3. Any previous cancer within 10 years (except basal cell carcinoma of the skin and adequately treated carcinoma-in-situ of the uterine cervix)
4. Concomitant chemotherapy
5. Patients with vasculitic conditions adversely affecting radiotherapy
6. Pregnancy
7. Other co-existing medical condition such that life expectancy is less than two years
8. Treatment with palliative intent

Date of first enrolment
01/08/2005

Date of final enrolment
31/07/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Aintree
Liverpool
United Kingdom
L9 7AL

Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

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

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	results	01/08/2013		Yes	No