

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

<b>Submission date</b> 10/05/2004	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/06/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/11/2015	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

### Contact name

Prof Martin Birchall

### Contact details

Clinical Sciences Centre  
University Hospital Aintree  
Lower Lane  
Liverpool  
United Kingdom  
L9 7AL

## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00334997

### Protocol serial number

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

**Study type(s)**

Treatment

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

Early stage glottic cancer

**Interventions**

Endoscopic excision or standard radiotherapy

**Intervention Type**

Mixed

**Primary outcome(s)**

Not provided at time of registration

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

31/07/2006

## Eligibility

**Key inclusion criteria**

1. Histologically confirmed squamous cell carcinoma of the glottic larynx, including tumours at the anterior commissure
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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

United Kingdom

England

## Study participating centre

University Hospital Aintree

Liverpool

United Kingdom

L9 7AL

## Sponsor information

### Organisation

University College London (UK)

### ROR

<https://ror.org/02jx3x895>

## Funder(s)

### Funder type

Charity

### Funder Name

Cancer Research UK

### Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

United Kingdom

## Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/08/2013		Yes	No