

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

Submission date 10/05/2004	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 22/06/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/11/2015	Condition category Cancer	☐ 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

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00334997

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.

Primary study design

Interventional

Study design

Randomised controlled trial

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?
Results article	results	01/08/2013		Yes	No