

Feasibility trial of chemoradiation or surgery for oesophageal cancer

Submission date 28/05/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 28/05/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/10/2022	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-pilot-study-learn-more-about-2-treatment-plans-cancer-foodpipe>

Contact information

Type(s)

Scientific

Contact name

Dr Joanna Nicklin

Contact details

MRC Health Services Research Collaboration
Canynge Hall
Whiteladies Road
Bristol
United Kingdom
BS8 2PR
+44
joanna.nicklin@bristol.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

2009-013877-16

Protocol serial number

7864

Study information

Scientific Title

Oesophageal squamous cell cancer: chemoradiotherapy versus chemotherapy and surgery - a feasibility study

Study objectives

The overall aim of this study is to determine whether a full multi-centre randomised trial of the two standard treatments for localised oesophageal squamous cell cancer is feasible.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North Somerset and South Bristol Research Ethics Committee, 30/10/2009, ref: 09/H0106/69

Study design

Multicentre randomisation or registration interventional treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Upper Gastro-Intestinal Cancer; Disease: Oesophageal Cancer

Interventions

1. Induction chemotherapy followed by oesophagectomy
2. Induction chemotherapy followed by chemoradiotherapy

Follow-up length: 24 months

Study entry: randomisation or registration

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The proportion (and number) of eligible patients randomised in the feasibility study, measured at randomisation

Key secondary outcome(s)

1. Health related quality of life, measured at 16 and 24 weeks, 12, 18 and 24 months post-randomisation or registration
2. Survival, measured at one and two years post-randomisation or registration
3. Treatment related toxicity and morbidity, measured during treatment and 16 and 24 weeks, and 12, 18 and 24 weeks post-randomisation or registration

Completion date

31/12/2011

Eligibility

Key inclusion criteria

1. Aged 18 years of age or older (either sex) on the date of first clinic appointment
2. With histologically confirmed oesophageal squamous cell cancer
3. With tumours staged as T2N0/1M0, T3N0/1M0, T4N0/1M0, where the T4 tumour involves the diaphragmatic crura or mediastinal pleura only (TNM classification)
4. With a total primary tumour and nodes less than 10 cm length
5. Considered sufficiently fit for both treatments in the trial by a surgeon and an oncologist, both of whom are members of the core multi-disciplinary team*
6. Willing to use contraception, if female and of child bearing age
7. Able to give informed written consent to participate in the randomised trial

*If the participant is of uncertain fitness for both treatments, then respiratory and cardiac function tests should be performed according to local practice within 4 weeks of randomisation. Suggested levels: forced expiratory volume in one second (FEV1) greater than 1.5 litres; cardiac ejection fraction greater than 50% of normal echocardiography.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

5

Key exclusion criteria

1. Concomitant or past malignancies within five years prior to randomisation, except basal or squamous cell carcinoma of the skin or in situ carcinoma of the cervix
2. Prior treatment for oesophageal cancer (not including photodynamic therapy or laser therapy for high grade dysplasia or carcinoma in situ)
3. Type I or II tumours of the oesophago-gastric junction with more than 2 cm gastric wall involvement (measured on EUS)
4. Previous treatment that compromises the ability to deliver definitive mediastinal chemoradiotherapy or to undergo oesophagectomy

Date of first enrolment

01/01/2010

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

MRC Health Services Research Collaboration

Bristol

United Kingdom

BS8 2PR

Sponsor information

Organisation

United Bristol Healthcare NHS Foundation Trust (UK)

ROR

<https://ror.org/04nm1cv11>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme

Results and Publications

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	results	15/07/2014	13/11/2019	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			26/10/2022	No	Yes