ISRCTN89052791 https://doi.org/10.1186/ISRCTN89052791

Feasibility trial of chemoradiation or surgery for oesophageal cancer

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

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

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Additional identifiers

EudraCT/CTIS number
2009-013877-16

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/01/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned sample size: 30; UK sample size: 30

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
England

United Kingdom

Study participating centre
MRC Health Services Research Collaboration
Bristol
United Kingdom
BS8 2PR

Sponsor information

Organisation
United Bristol Healthcare NHS Foundation Trust (UK)

Sponsor details
Trust Headquarters
Marlborough Street
Bristol

England
United Kingdom
BS1 3NU

Sponsor type
Hospital/treatment centre

Website
http://www.uhbristol.nhs.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

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