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Cisplatin, capecitabine, and radiation therapy with or without cetuximab in treating patients with oesophageal cancer

Submission date 20/04/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/05/2006	**Overall study status** Completed	
Last Edited 19/03/2020	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-chemoradiotherapy-with-or-without-cetuximab-for-cancer-of-the-food-pipe

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00509561

Clinical Trials Information System (CTIS)
2006-002241-37

Protocol serial number
WCTU01

Study information

Scientific Title
A randomised phase II/III multicentre clinical trial of definitive chemoradiation, with or without cetuximab, in carcinoma of the oesophagus

Acronym
SCOPE 1

Study objectives
Patients with histologically confirmed carcinoma of the oesophagus, squamous cell or adenocarcinoma, (considered suitable for definitive chemoradiation by an accredited multi-disciplinary team [MDT] including a specialist upper gastrointestinal [GI] surgeon), will be randomised to receive definitive chemoradiation treatment (CRT) with or without cetuximab.

On 11/02/2009 the overall trial start and end dates were amended. The initial dates at the time of registration were:
Initial overall trial start date: 01/06/2007
Initial overall trial end date: 01/06/2012
All other changes to this record can be found in the relevant field under the update date of 11 /02/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee for Wales gave multicentre approval on 17/04/2007

Primary study design
Interventional

Study design
Two-arm open randomised phase II/III trial with a 1:1 randomisation ratio

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Oesophageal cancer

Interventions
Control arm: chemoradiation
Experimental arm: chemoradiation plus cetuximab

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Cisplatin, capecitabine, radiation therapy, cetuximab

Primary outcome(s)
Phase II: treatment failure
Phase III: overall survival

Key secondary outcome(s)
Phase II:
1. Toxicity
2. Feasibility

Phase III:
1. Toxicity
2. Health economics
3. Quality of life
4. Quality assurance

Completion date
01/02/2016

Eligibility

Key inclusion criteria
Amended 11/02/2009:
The following points of the below criteria have been amended as follows:
2. Histologically confirmed carcinoma of the oesophagus (adenocarcinoma, squamous cell, or undifferentiated) or Siewert type 1 tumour of the gastro-oesophageal junction (GOJ) or Siewert Type 2 with no more than 2 cm mucosal extension into the stomach
3. Tumours staged with endoscopic ultrasonography (EUS) and spiral computerised tomography (CT) scan to be T1-4N0-1 confirming localised, non-metastatic disease
7. Adequate cardio-respiratory function for definitive CRT. (Echo or multiple-gated acquisition left ventricular (MUGA LV) function greater than 40% (no acute coronary event in previous six months, myocardial infarction or unstable angina), forced expiratory volume in one second (FEV1) greater than 1 litre)
8. Adequate renal function for definitive CRT (renal glomerular filtration rate greater than 60 ml /min (calculated using Cockroft formula with ethylenediaminetetraacetic acid (EDTA) if predicted less than 60 ml/min
9. Written informed consent to participate in the trial

Initial information at time of registration:
1. Patients older than 18 years of age who have been selected to receive potentially curative definitive chemo-radiation
2. Histologically confirmed carcinoma of the oesophagus (adenocarcinoma or squamous cell) or Siewert type 1 tumour of the gastro-oesophageal junction (GOJ)
3. Tumours staged with endorectal ultrasonography (EUS) and spiral computerised tomography (CT) scan to be T1-4N0-1 confirming localised, non-metastatic disease
4. Total disease length (primary tumour and lymph nodes) less than 10 cm defined by EUS
5. World Health Organization (WHO) performance status 0 or 1
6. Patients physically and psychologically fit and willing to receive definitive chemoradiation with or without cetuximab

7. Adequate cardio-respiratory function for definitive CRT. Echo or multiple-gated acquisition left ventricular (MUGA LV) function greater than 40% (no acute coronary event in previous six months, myocardial infarction or unstable angina), forced expiratory volume in one second (FEV1) greater than 1 litre, renal glomerular filtration rate greater than 60 ml/min (calculated using Cockroft formula with ethylenediaminetetraacetic acid (EDTA) if predicted less than 60 ml /min).
8. Written informed consent to participate in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Amended 11/02/2009:
The following points of the below criteria have been amended as follows:
3. Patients with previous treatment for malignancy, which will compromise ability to deliver definitive mediastinal chemoradiation or may compromise survival

Initial information at time of registration:
1. Patients who have had previous treatment for oesophageal carcinoma
2. Patients with metastatic disease i.e. M1a/coeliac nodes or M1b
3. Patients with previous treatment for malignancy, which will compromise ability to deliver definitive mediastinal chemoradiation
4. Patients with significant (greater than 2 cm) extension of tumour into the stomach

Date of first enrolment
07/02/2008

Date of final enrolment
06/02/2011

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Velindre Hospital
Cardiff
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CF14 2TL

Sponsor information

Organisation
Velindre NHS Trust (UK)

ROR
https://ror.org/05ntqkc30

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) - Clinical Trials Advisory and Awards Committee (CTAAC) (ref: C20177/A6386)

Results and Publications

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	01/06/2013		Yes	No
Results article	results	14/03/2017		Yes	No
Protocol article	protocol	28/10/2011		Yes	No
Basic results				No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes

Study website	Study website	11/11/2025	11/11/2025	No	Yes