

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/05/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/03/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2006-002241-37

ClinicalTrials.gov (NCT)

NCT00509561

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

Study design

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

Primary study design

Interventional

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 Cockcroft 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 Cockcroft 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
United Kingdom
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