

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

<b>Submission date</b> 20/04/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/05/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/03/2020	<b>Condition category</b> 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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### Contact details

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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?
<a href="#">Results article</a>	results	01/06/2013		Yes	No
<a href="#">Results article</a>	results	14/03/2017		Yes	No
<a href="#">Protocol article</a>	protocol	28/10/2011		Yes	No
<a href="#">Basic results</a>				No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Plain English results</a>				No	Yes

[Study website](#)

Study website

11/11/2025 11/11/2025 No

Yes