

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

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

## Study website

<http://www.wctu.org.uk>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Tom Crosby

### Contact details

Velindre Hospital  
Whitchurch  
Cardiff  
United Kingdom  
CF14 2TL

## Additional identifiers

### EudraCT/CTIS number

2006-002241-37

### IRAS number

### ClinicalTrials.gov number

NCT00509561

## **Secondary identifying numbers**

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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

Can be found at: <http://www.wctu.org.uk/scopedocs.htm>

**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 measure**

Phase II: treatment failure

Phase III: overall survival

**Secondary outcome measures**

Phase II:

1. Toxicity
2. Feasibility

Phase III:

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

**Overall study start date**

07/02/2008

**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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

440 (420 as of 11/02/2009)

### **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)

**Sponsor details**

Velindre Hospital

Whitchurch

Cardiff

Wales

United Kingdom

CF14 2TL

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.wales.nhs.uk/sites3/home.cfm?orgid=34>

**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

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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="#">Basic results</a>         |          |              |            | No             | No              |
| <a href="#">Plain English results</a> |          |              |            | No             | Yes             |
| <a href="#">Protocol article</a>      | protocol | 28/10/2011   |            | Yes            | No              |
| <a href="#">Results article</a>       | results  | 01/06/2013   |            | Yes            | No              |
| <a href="#">Results article</a>       | results  | 14/03/2017   |            | Yes            | No              |