

# Capecitabine and oxaliplatin combination chemotherapy in gall bladder or biliary tract cancer patients

<b>Submission date</b> 29/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/11/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Cancer of the biliary tract (gallbladder and bile duct) is a relatively rare form of cancer. The gall bladder is a small pouch which stores bile (a liquid essential for the breakdown of fats in the diet) made by the liver. Cancer of the gall bladder or bile duct that has spread and cannot be removed by an operation (inoperable) is often treated with chemotherapy. The aim of this study is to find out how effective a combination of two drugs, called capecitabine and oxaliplatin, is in treating these cancers as measured by shrinking the tumour on a CT scan. The study will also try to find out what side-effects are experienced by patients with these cancers when treated with this chemotherapy regimen.

### Who can participate?

Adults with inoperable cancer of the gall bladder or bile duct.

### What does the study involve?

Patients receive up to 6 cycles of chemotherapy. One cycle consists of capecitabine tablets given by mouth twice a day for 14 days. The oxaliplatin is given as a drip into a vein over 2 hours on the first day. This cycle of treatment is repeated every 3 weeks. A CT scan will be performed before starting treatment and then after 3 and 6 cycles of treatment to see what effect there has been on the size of the tumour.

### What are the possible benefits and risks of participating?

There is a possibility that the treatment used in this study could help to shrink the tumour, however this is not certain. There is a risk that participants will experience side effects from the chemotherapy, including hair loss, sickness and vomiting, pain, tingling and numbness in the hands and feet, skin rash, blisters and peeling of the skin on the hands and feet, increased risk of infections which may be serious, or bruising.

### Where is the study run from?

Five hospitals in Scotland, Ireland and the North of England (UK)

When is the study starting and how long is it expected to run for?  
July 2003 to January 2006

Who is funding the study?  
North Glasgow University Hospitals NHS Division (UK)

Who is the main contact?  
Ms Eileen Soulis  
eileen.soulis@glasgow.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Eileen Soulis

**Contact details**  
Clinical Trial Co-ordinator  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2004-000928-32

**Protocol serial number**  
1744

## Study information

**Scientific Title**  
A phase II study of capecitabine and oxaliplatin combination chemotherapy in patients with inoperable adenocarcinoma of the gall bladder or biliary tract

**Acronym**  
BILXELOX (GI85)

**Study objectives**

The primary objective as stated in the study protocol is to determine the objective response rate (complete or partial), by the response evaluation criteria in solid tumours (RECIST) criteria, of capecitabine and oxaliplatin combination chemotherapy in patients with inoperable adenocarcinoma of the gall bladder or biliary tract.

Using an optimal two-stage Simon design, a total of 43 patients gives 80% power at the 5% significance level to detect a response rate of greater than or equal to 40%, at which point it would be appropriate to consider further studies with this regimen, from a response rate of 20%, below which this regimen would not be pursued in subsequent studies.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

West of Scotland REC 1, 15/05/2003, ref: MREC 03/8/027

### **Study design**

Non-randomised interventional treatment trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Topic: National Cancer Research Network; Subtopic: Upper Gastro-Intestinal Cancer; Disease: Biliary Tract, Gall Bladder

### **Interventions**

1. Capecitabine, twice daily (BID) for 14 days every 21 days, 1000 mg/m<sup>2</sup>
2. Oxaliplatin, once daily (OD) once every 21 days, 130 mg/m<sup>2</sup>

Duration of treatment was 18 weeks (maximum of 6 cycles), duration of follow-up was until death or progression, or at the investigator's discretion.

### **Intervention Type**

Other

### **Phase**

Phase II

### **Primary outcome(s)**

Objective response rate (complete and partial) by RECIST of capecitabine and oxaliplatin combination, assessed after 13 patients recruited.

### **Key secondary outcome(s)**

Measured after 43 patients are recruited:

1. Toxicity
2. Progression-free survival
3. Overall survival

**Completion date**

20/01/2006

## Eligibility

**Key inclusion criteria**

1. Histologically or cytologically proven adenocarcinoma of the gall bladder or biliary tract
2. Inoperable disease as determined by radiological assessment, laparotomy or laparoscopy
3. At least one site of unidimensional measurable disease. Lesions must be at least 10 mm in diameter if measured on a spiral computed tomography (CT) scan.
4. Performance status greater than or equal to 2 (Eastern Cooperative Oncology Group [ECOG])
5. Adequate renal function (serum creatinine less than 1.5 x the upper limit of the normal reference range) and creatinine clearance greater than 50 ml/min as calculated by the Cockcroft-Gault formula. Patients with creatinine clearance less than or equal to 50 mL/min by the Cockcroft-Gault formula are eligible if the creatinine clearance is greater than 50 mL/min if measured by an EDTA assessment.
6. Written informed consent
7. Aged greater than 18 years, either sex
8. No prior chemotherapy for advanced disease
9. Able to reliably tolerate and comply with oral medication (capecitabine)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

43

**Key exclusion criteria**

1. Any evidence of uncontrolled cardiac disease or any other serious medical or psychiatric disorder that would be a contra-indication for prescribing this chemotherapy regimen
2. Pregnancy. Women of child-bearing potential not taking adequate contraception, and women who are breast feeding will also be excluded.
3. No prior or concurrent malignancy other than basal cell carcinoma of the skin or in situ neoplasia of the cervix uteri
4. Inadequate haematological function as defined by:
  - 4.1. Haemoglobin (Hb) less than 10 g/dl
  - 4.2. Neutrophil count less than  $1.5 \times 10^9/l$
  - 4.3. Platelets less than  $100 \times 10^9/l$

5. Deranged liver function tests: serum bilirubin greater than 2.5 x upper limit of normal reference range for laboratory; transaminases greater than 5 x upper limit of normal reference range
6. Life expectancy less than 3 months
7. Any chemotherapy, radiotherapy, hormonal or immunotherapy within the last 4 weeks
8. Patients with a lack of physical integrity of the gastrointestinal (GI) tract leading to a malabsorption syndrome or intestinal obstruction that would impair administration or absorption of oral therapy
9. Patients with greater than grade 1 peripheral sensory neuropathy
10. Patients with known sensitivity to fluoropyrimidines or oxaliplatin

**Date of first enrolment**

10/07/2003

**Date of final enrolment**

20/01/2006

## **Locations**

**Countries of recruitment**

United Kingdom

England

Scotland

Ireland

**Study participating centre**

**Beatson West of Scotland Cancer Centre**

Cancer Research UK Clinical Trials Unit  
(partner in CaCTUS - Cancer Clinical Trials Unit Scotland)  
Level 0  
1053 Great Western Road  
Glasgow  
United Kingdom  
G12 0YN

**Study participating centre**

**St James Hospital**

James's St  
Dublin  
Ireland  
8

**Study participating centre**  
**Ninewells Hospital**  
Dundee  
United Kingdom  
DD2 1UB

**Study participating centre**  
**Western General Hospital**  
Crewe Road South  
Edinburgh  
United Kingdom  
EH4 2XU

**Study participating centre**  
**Newcastle General Hospital**  
Westgate Road  
Newcastle upon Tyne  
United Kingdom  
NE4 6BE

## **Sponsor information**

**Organisation**  
NHS Greater Glasgow and Clyde

**ROR**  
<https://ror.org/05kdz4d87>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
North Glasgow University Hospitals NHS Division (UK)

## **Results and Publications**

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	12/03/2016	28/11/2019	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes