ISRCTN40839737 https://doi.org/10.1186/ISRCTN40839737

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

Submission date	Recruitment status	[_] Prospectively registered
29/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/11/2019	Cancer	

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
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Study website
http://www.west-cancer-trials.org/reports/rwservlet?public_study_desc+studyno=GI85

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number
2004-000928-32

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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^2
2. Oxaliplatin, once daily (OD) once every 21 days, 130 mg/m^2

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

Secondary outcome measures
Measured after 43 patients are recruited:
1. Toxicity
2. Progression-free survival
3. Overall survival

Overall study start date
10/07/2003

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 Cockroft-Gault formula. Patients with creatinine clearance less than or equal to 50 mL/min by the Cockroft-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

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Planned sample size: 43

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 x 10^9/l
4.3. Platelets less than 100 x 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
England

Ireland

Scotland

United Kingdom

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
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G12 0YN

Study participating centre
St James Hospital
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8

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Ninewells Hospital
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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

Sponsor details
Research and Development Central Office
Tennent Institute
38 Church Street
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G11 6NT

Sponsor type
Government

Website
http://www.ngt.org.uk/research/home.htm

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
North Glasgow University Hospitals NHS Division (UK)

Results and Publications

Publication and dissemination plan
1. Presentation (published abstract) at an international meeting
2. Planned publication in BMC Research Notes

Intention to publish date
30/06/2016

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?

Results article	results	12/03/2016	28/11/2019	Yes	No