

Gemcitabine, alone or in combination with cisplatin, in patients with advanced or metastatic cholangiocarcinomas and other biliary tract tumours

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		<input type="checkbox"/> Protocol
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/09/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1348

Study information

Scientific Title

Gemcitabine, alone or in combination with cisplatin, in patients with advanced or metastatic cholangiocarcinomas and other biliary tract tumours: a multicentre, randomised phase II study

Acronym

ABC-01

Study objectives

There is no standard chemotherapy for patients with advanced biliary tract cancer. Gemcitabine has shown some activity in early phase II studies. Cisplatin is known to synergise with gemcitabine in other tumour types (including lung, head and neck and bladder cancers). The specific sequence of cisplatin followed by gemcitabine appears optimal in pre-clinical testing. Cisplatin/gemcitabine combinations have been reported in pancreatic cancer in various schedules and we have completed a phase I/II study of weekly co-administration of both drugs in advanced pancreatic cancer demonstrating good tolerability.

The aim of this study was to examine this regimen in biliary tumours using a randomised phase II study of gemcitabine as a single agent and the cisplatin/gemcitabine combination. Before undertaking a full phase III trial in comparison with other regimens (or best supportive care) this study assessed the relative merits of each treatment arm in terms of efficacy, feasibility and tolerability.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NorthWest MREC approved on the 2nd August 2002 (ref: 02/8/32)

Study design

Multicentre randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please contact Juan.Valle@christie.nhs.uk 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

This was an investigator-led, multicentre, randomised phase II study of weekly (3 weeks in every 4, x 6 cycles) of gemcitabine IV 1000 mg/m² as a single agent (control) or preceded by cisplatin IV 25 mg/m² (on a 2 weeks in every 3-cycle, x 8 cycles) in patients with histologically proven, inoperable or metastatic cholangiocarcinoma or other biliary tract tumours not previously treated with chemotherapy.

A minimum of 2 cycles was required to assess tumour status and the maximum period of therapy was 24 weeks (six 4-weekly cycles of single agent gemcitabine, eight 3-weekly cycles of cisplatin /gemcitabine). Assessment by CT scan every 12 weeks during treatment was used to determine tumour status.

Study entry: Single randomisation only

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Gemcitabine, cisplatin

Primary outcome measure

To assess the efficacy in terms of 6-month progression-free rate for both treatment arms

Secondary outcome measures

1. Overall survival
2. Response rate, evaluated after 12 and 24 weeks of treatment via CT, according to WHO guidelines
3. Toxicity assessment (adverse events [AEs] graded according to National Cancer Institute Common Terminology Criteria for Adverse Events [NCI CTCAE] criteria)

Overall study start date

11/01/2002

Completion date

14/05/2004

Eligibility

Key inclusion criteria

1. Histologically or cytologically verified, non-resectable or recurrent/metastatic cholangiocarcinoma (intra- or extra-hepatic), gallbladder or ampullary carcinoma
2. Measurable, non-measurable or evaluable disease on computed tomography (CT) or magnetic resonance (MR) scanning. Radiological assessments must be done within 4 weeks of starting chemotherapy.

3. Karnofsky performance status greater or equal to 60
4. Age greater than or equal to 18 years, either sex
5. Life expectancy greater than 3 months
6. Adequate renal function with serum urea and serum creatinine less than 1.5 times upper limit of normal (ULN) and glomerular filtration rate greater or equal to 60 ml/min as measured by creatinine clearance or EDTA or calculated by using the Cockcroft formula
7. Adequate haematological function:
 - 7.1. Haemoglobin greater or equal to 10 g/dl
 - 7.2. White blood cell count (WBC) greater or equal to $3.0 \times 10^9/L$
 - 7.3. Absolute neutrophil count (ANC) greater or equal to $1.5 \times 10^9/L$
 - 7.4. Platelet count greater or equal to $100,000/mm^3$
8. Adequate liver function:
 - 8.1. Total bilirubin less than 30 mmol/L
 - 8.2. Alanine aminotransferase (ALT), aspartate aminotransferase (AST) and alkaline phosphatase less than or equal to 3 x ULN (unless liver metastases are present, when they can be less than or equal to 5 x ULN)
9. Adequate biliary drainage, with no evidence of ongoing infection
10. Women of child bearing age MUST have a negative pregnancy test prior to study entry AND be using an adequate contraception method, which must be continued for 3 months after the study, unless child bearing potential has been terminated by surgery/radical radiotherapy
11. Previous radiotherapy (or chemo-radiotherapy) is allowed, as long as the measurable disease to be evaluated in this study does not fall within the previous radiotherapy treatment field
12. Prior photodynamic therapy is allowed, provided there has been clear radiological evidence of disease progression
13. Patients must not have a history of other malignant diseases other than adequately treated non-melanotic skin cancer or in-situ carcinoma of the uterine cervix
14. Patients must have given written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

Planned sample size: 86; UK sample size: 86

Key exclusion criteria

1. Incomplete recovery from previous surgery or unresolved biliary tree obstruction
2. Any previous chemotherapy (with the exception of low-dose chemotherapy used as a radiosensitiser during combined modality chemo-radiotherapy)
3. Previous investigational agent in the last 12 weeks
4. Any evidence of severe or uncontrolled systemic diseases which, in the view of the investigator, makes it undesirable for the patient to participate in the trial
5. Evidence of significant clinical disorder or laboratory finding which, in the opinion of the

investigator makes it undesirable for the patient to participate in the trial

6. Any patient with a medical or psychiatric condition that impairs their ability to give informed consent

7. Any other serious uncontrolled medical conditions

8. Clinical evidence of metastatic disease to brain

9. Any pregnant or lactating woman

Date of first enrolment

11/01/2002

Date of final enrolment

14/05/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Medical Oncology

Manchester

United Kingdom

M20 4BX

Sponsor information

Organisation

Christie Hospital NHS Foundation Trust (UK)

Sponsor details

550 Wilmslow Road

Manchester

England

United Kingdom

M20 4BX

Sponsor type

Hospital/treatment centre

Website

<http://www.christie.nhs.uk/>

ROR

Funder(s)

Funder type

Industry

Funder Name

Lilly Oncology (UK)

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?
Results article	results	18/08/2009		Yes	No