ISRCTN96194255 https://doi.org/10.1186/ISRCTN96194255

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

**Submission date**
12/05/2010

**Recruitment status**
No longer recruiting

**Registration date**
12/05/2010

**Overall study status**
Completed

**Last Edited**
10/09/2019

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
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

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

### Key secondary outcome(s))
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)

### 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 tompgraphy (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 Cockroft 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 x 10^9/L
7.3. Absolute neutrophil count (ANC) greater or equal to 1.5 x 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
Not Specified

### 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
United Kingdom

England

### Study participating centre
**Department of Medical Oncology**
Manchester
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M20 4BX

# Sponsor information

### Organisation
Christie Hospital NHS Foundation Trust (UK)

### ROR
https://ror.org/03v9efr22

# Funder(s)

### Funder type
Industry

### Funder Name
Lilly Oncology (UK)

# 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? |
|---|---|---|---|---|---|
| | results | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Results article | | 18/08/2009 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |