

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

<b>Submission date</b> 15/02/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/03/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-chemotherapy-for-advanced-cancer-of-the-bile-duct-or-gallbladder>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

Clinical Trials Information System (CTIS)

2004-004882-14

ClinicalTrials.gov (NCT)

NCT00262769

**Protocol serial number**

N/A

## 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 III study

**Acronym**

ABC-02

**Study objectives**

The aim of this trial is to compare gemcitabine alone to gemcitabine and cisplatin, in patients with advanced or metastatic biliary tract tumours, in order to establish a standard treatment. This is a multicentre, randomised, phase III trial, designed by members of the Trial Management Group in consultation with the National Cancer Research Institute (NCRI) Upper Gastrointestinal Clinical Studies Group.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

No ethics information provided at time of registration.

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Advanced or metastatic biliary tract carcinoma

**Interventions**

Randomisation between:

Arm A: Gemcitabine 1000 mg/m<sup>2</sup> intravenous (IV) infusion on days one, eight and 15 of each 28 day cycle (six cycles in total)

Arm B: Gemcitabine 1000 mg/m<sup>2</sup> and Cisplatin 25 mg/m<sup>2</sup> IV infusion on days one and eight of each 21 day cycle (eight cycles in total)

**Intervention Type**

Drug

**Phase**

Phase III

**Drug/device/biological/vaccine name(s)**

Gemcitabine, cisplatin

**Primary outcome(s)**

The primary objective of this trial is to determine whether the overall survival of patients treated with gemcitabine compared with patients treated with gemcitabine and cisplatin in biliary tract cancer.

**Key secondary outcome(s)**

The secondary objective is to determine the progression-free survival, toxicity and quality of life of patients treated with gemcitabine compared with patients treated with gemcitabine and cisplatin in biliary tract cancer.

**Completion date**

31/03/2009

**Eligibility**

**Key inclusion criteria**

1. Over 16 years of age
2. Histologically/cytologically confirmed biliary tract carcinoma
3. Unsuited for surgery
4. Adequate renal, haematological and liver function
5. Adequate biliary drainage
6. Eastern Cooperative Oncology Group (ECOG) performance score of zero, one or two
7. Life expectancy of greater than 12 weeks
8. Patient consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. No concurrent treatment for metastatic disease
2. Other/prior malignancy or intercurrent disease precluding trial entry
3. Pregnancy/lactation
4. Unable to give consent

NB. Patients with impaired hearing must be made aware of potential ototoxicity

**Date of first enrolment**

01/03/2005

**Date of final enrolment**

31/03/2009

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

Royal Free & University College Medical School

London

United Kingdom

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## Sponsor information

**Organisation**

University College London (UK)

**ROR**

<https://ror.org/02jx3x895>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Clinical Trials Advisory and Awards Committee (CTAAC) Ref: C1813/A4853

## 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?
<a href="#">Results article</a>	results	08/04/2010		Yes	No
<a href="#">Plain English results</a>				No	Yes