

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

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

EudraCT/CTIS number

2004-004882-14

IRAS number

ClinicalTrials.gov number

NCT00262769

Secondary identifying numbers

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

Secondary study design

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

Advanced or metastatic biliary tract carcinoma

Interventions

Randomisation between:

Arm A: Gemcitabine 1000 mg/m² intravenous (IV) infusion on days one, eight and 15 of each 28 day cycle (six cycles in total)

Arm B: Gemcitabine 1000 mg/m² and Cisplatin 25 mg/m² 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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/03/2005

Completion date

31/03/2009

Eligibility

Key inclusion criteria

1. Over 16 years of age
2. Histologically/cytologically confirmed biliary tract carcinoma
3. Unsuitable 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

Age group

Adult

Sex

Both

Target number of participants

400

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**

England

United Kingdom

Study participating centre

Royal Free & University College Medical School

London

United Kingdom

W1W 7BS

Sponsor information**Organisation**

University College London (UK)

Sponsor details

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Sponsor type
University/education

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

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?
Plain English results				No	Yes
Results article	results	08/04/2010		Yes	No