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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

Registration date
21/03/2005

Overall study status
Completed

Last Edited
19/10/2018

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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/m^2 intravenous (IV) infusion on days one, eight and 15 of each 28 day cycle (six cycles in total)
Arm B: Gemcitabine 1000 mg/m^2 and Cisplatin 25 mg/m^2 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