

Biliary stenting with or without photodynamic therapy in treating patients with locally advanced, recurrent, or metastatic cholangiocarcinomas or other biliary tract tumours that cannot be removed by surgery

Submission date 10/03/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/04/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/07/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-having-a-stent-with-or-without-photodynamic-therapy-for-symptoms-of-advanced-biliary-tract-cancer>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2005-001173-96

ClinicalTrials.gov (NCT)

NCT00513539

Protocol serial number

PHOTOSTENT-02

Study information

Scientific Title

Porfimer Sodium photodynamic therapy plus stenting versus stenting alone in patients with advanced or metastatic cholangiocarcinomas and other biliary tract tumours: a multicentre, randomised, phase II/III study

Acronym

PHOTOSTENT-02

Study objectives

The aim of this trial is to determine whether Photofrin® (porfimer sodium) photodynamic therapy in addition to standard treatment confers an overall survival benefit in patients with locally advanced non-resectable biliary tract carcinoma. 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. Patients entering the trial will be randomised to receive either a biliary stent or photodynamic therapy plus a stent. After 3 and 6 months patients will have a computed tomography (CT) scan to determine tumour response. After this patients will be seen as outpatients on a 3-monthly basis. CT scans and routine investigations will be performed at each outpatient visits. Patients who agree will complete quality of life questionnaires at baseline, and then again at 1, 3 and 6 months post-treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West Multi-Centre REC, 20/06/2005, ref: 05/MRE08/32; CTA: 21266/0005/001

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Advanced or metastatic biliary tract cancer

Interventions

Randomisation between:

Arm A: Biliary stenting alone

Arm B: Biliary stenting plus photodynamic therapy

Please note that as of 18/01/10 this trial is closed to recruitment.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Photofrin®

Primary outcome(s)

Overall survival, i.e. death

Key secondary outcome(s)

1. Progression-free survival, measured by means of CT scanning carried out every three months until evidence of progression is identified
2. Toxicity, collected at baseline and 1 month post trial treatment for patients on the PDT arm we also collect toxicity data 7 days post-PDT treatment
3. Quality of life, collected at baseline 1, 3 and 6 months post-trial treatment

Completion date

01/12/2009

Eligibility**Key inclusion criteria**

1. Aged over 16 years of age, either sex
2. Histologically/cytologically confirmed biliary tract carcinoma, unsuitable for surgery
3. Adequate biliary drainage
4. World Health Organization (WHO) performance score of 0, 1, 2 or 3
5. Life expectancy of greater than 12 weeks

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

All

Total final enrolment

93

Key exclusion criteria

1. Receiving concurrent treatment for metastatic disease
2. Other/prior malignancy or intercurrent disease
3. Unable to give consent
4. Shows symptoms of porphyria
5. Pregnant or lactating

Date of first enrolment

07/07/2007

Date of final enrolment

01/12/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Middlesex Hospital

London

United Kingdom

W1T 3AA

Sponsor information

Organisation

University College London (UK)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Axcan Pharma Inc. (USA) - educational grant

Funder Name

Cancer Research UK (CRUK) (UK) - Clinical Trials Advisory and Awards Committee (CTAAC) - funding pending

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2012		Yes	No
Results article	results	23/07/2018		Yes	No
Plain English results			11/07/2023	No	Yes