ISRCTN87712758 https://doi.org/10.1186/ISRCTN87712758

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

Registration date
27/04/2005

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Cancer

[X] 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-having-a-stent-with-or-without-photodynamic-therapy-for-symptoms-of-advanced-biliary-tract-cancer

Contact information

Type(s)
Scientific

Contact name
Dr Stephen Pereira

Contact details
Department of Gastroenterology
Middlesex Hospital
Mortimer Street
London
United Kingdom
W1T 3AA

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 ll/lll study

Acronym
PHOTOSTENT-02

Study objectives
The aim of this trial is to determine whether Photofrin® (profimer 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 photodymanic 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			11/07/2023	No	Yes