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

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## Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT00513539

**Clinical Trials Information System (CTIS)**

2005-001173-96

### 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

### Primary study design
Interventional

### Study design
Randomized controlled trial

### 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 |