

# 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

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

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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 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?
<a href="#">Results article</a>	results	01/12/2012		Yes	No
<a href="#">Results article</a>	results	23/07/2018		Yes	No
<a href="#">Plain English results</a>			11/07/2023	No	Yes