BILCAP: A randomised clinical trial evaluating adjuvant chemotherapy with capecitabine compared to expectant treatment alone following surgery for biliary tract cancer

Trial development group: **Prof J Primrose (Chief Investigator)**, Dr John Bridgewater, Prof D Cunningham, Prof J Dunn, Prof J Garden, Prof P Johnson, Prof J Neoptolemos, Mr G Poston, Mr D Sherlock, Dr J Valle, Dr H Wasan, on behalf of the NCRI Upper GI CSG.

Rationale for the study: Currently the benefit of adjuvant treatment following surgery for biliary tract cancer remains unclear although there are now data to support adjuvant chemotherapy in bowel and pancreatic malignancy. The best available evidence suggests that in this setting a fluoropyrimidine such as capecitabine may be the best option. This study aims to evaluate adjuvant chemotherapy with capecitabine in patients who have undergone complete macroscopic resection for biliary tract cancer, compared to expectant treatment alone. The primary endpoint will be 2-year survival, and secondary endpoints 5-year survival, relapse free interval, toxicity, Quality of Life and Health Economics.

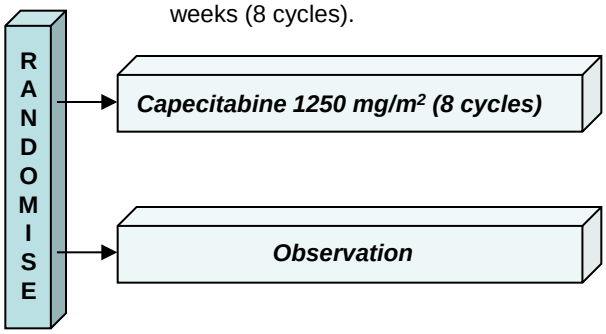
Study Design

A two-arm, multi-centre phase III randomised study for patients who have undergone a macroscopically complete surgical resection of a biliary tract cancer.

Eligible patients will be randomised between:

Control Arm: Observation

Treatment Arm: Capecitabine 1250mg/m^2 given PO twice a day on day 1 to 14 of a 3 weekly cycle, for 24 weeks (8 cycles).



Further treatment as indicated on progression.

All patients will be followed up for 5 years post-randomisation.

Study Aim

To investigate the role of adjuvant capecitabine in the treatment of macroscopically complete surgical resection of biliary tract cancer.

Primary Endpoint

- 2-year survival

Secondary Endpoints

- 5-year survival
- Relapse free survival
- Toxicity
- Quality of Life
- Health Care Economics

For Further Information

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Study organisation

- Trial aims to recruit 410 patients
- Sponsored by University of Southampton
- Co-ordinated by Cancer Research UK Clinical Trials Unit (University of Birmingham)
- NCRN trial funded by Cancer Research UK

Inclusion & Exclusion Criteria

Inclusion Criteria

- Histologically confirmed biliary tract cancer (intrahepatic or extrahepatic cholangiocarcinoma or muscle invasive gallbladder cancer or cancer of the distal bile duct)
- Macroscopically complete resection with curative intent
- Radical surgical approach including liver resection, pancreatic resection, or less commonly both
- Adequate renal, haematological & liver function
- Adequate surgical biliary drainage - no evidence of infection
- Age ≥ 18 years
- ECOG performance status ≤ 2
- Not of childbearing potential or must use approved contraception
- Written informed consent
- Able to start treatment within 12 weeks of surgery

Exclusion Criteria

- Pancreatic or ampullary cancer, mucosal gallbladder cancer
- Incomplete recovery from previous surgery or unresolved biliary tree obstruction
- Use of other investigational agents within 4 weeks of planned entry into the study
- History of second malignancy within 5 years of trial entry, (except adequately treated cervical carcinoma-in-situ or non-melanotic skin cancer).
- Previous chemotherapy or radiotherapy given for biliary tract cancer
- Serious co-existing medical condition including a potential serious infection.
- Evidence of significant clinical disorder or laboratory finding which, in the opinion of the investigator makes it undesirable for the patient to participate in the trial
- Psychological, familial, sociological or geographical factors considered likely to prevent compliance with the protocol.
- Any other serious uncontrolled medical conditions
- Pregnant or breastfeeding women

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