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

J. A. Bridgewater, C. Stubbs, J. N. Primrose, National Cancer Research Institute (UK) Upper Gastrointestinal Studies Group; UCL, London, United Kingdom; Cancer Research UK Clinical Trials Unit (CRCTU), Birmingham, United Kingdom; Southampton General Hospital, Southampton, United Kingdom

Background: Biliary tract tumours are relatively rare, accounting for 0.7% of malignant tumours in adults, with approximately 1200 new cases registered each year in England and Wales. The 1-year and 5-year survival is poor at 22% and 9% respectively. Approximately 15-20% of cases are suitable for surgical resection but the outlook remains poor with survival at 5 years approximately 15%. Most tumours are advanced at presentation and are unsuitable for surgical resection. Methods: BILCAP is a multi-centre prospective, randomised phase III trial investigating the role of adjuvant chemotherapy with oral fluoropyrimidine (capecitabine) in patients following potentially curative surgical resection of a biliary tract cancer. Patients who have undergone macroscopically complete surgical resection will be randomised to receive either adjuvant chemotherapy with capecitabine or observation. The study is supervised by the National Cancer Research Institute (UK) Upper Gastrointestinal Studies Group and funded by Cancer Research UK. Results: The primary endpoint is progression free survival (DFS) at 2 years. The intention is to increase 2 year DFS from 15 to 28%. This will require 360 patients enabling a 2-sided significance level of 5% and 80% power. Secondary endpoints are 5-year survival, toxicity, quality of life and health economics. Toxicity has been acceptable. Conclusions: 202 of 360 patients have been successfully recruited to date. With approximately 200 resections for biliary tract cancer per year in the UK, BILCAP has recruited more than 25% of all resected patients in the UK for the last 3 years (51 pts in 2008, 53 pts in 2009 and 73 patients in 2010) and 36% in 2010. As such it is the most successful adjuvant study in biliary tract cancer and will complete accrual in Q1 2012. The results of BILCAP will define the international standard of care for patients with resected biliary tract cancer. Further detail on recruitment and toxicity will be presented. ISRCTN Number: ISRCTN72785446, EudraCT Number: 2005-003318-13.