gastrointestinal tumours, non-colorectal

ABC-06: A RANDOMISED PHASE III, MULTI-CENTRE, OPEN-LABEL STUDY OF ACTIVE SYMPTOM CONTROL (ASC) ALONE OR ASC WITH OXALIPLATIN / 5-FU CHEMOTHERAPY FOR PATIENTS WITH LOCALLY ADVANCED / METASTATIC BILIARY TRACT CANCERS (ABC) PREVIOUSLY TREATED WITH CISPLATIN / GEMCITABINE CHEMOTHERAPY.

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Background: Since the randomized NCRN phase III ABC-02 trial, there exists level A evidence for first-line chemotherapy with cisplatin and gemcitabine combination in ABC. To date, no robust evidence is available supporting the use of second-line treatment, where only a few retrospective and prospective (phase II) studies employing multiple different chemotherapy schedules have been conducted (level C). Therefore, currently, ASC (i.e. proactive management of biliary obstruction / sepsis, etc.) is the standard of care for second-line treatment in ABC. After progression on a first-line gemcitabine-based chemotherapy switching to a fluoropyrimidine-based schedule may be considered appropriate. Moreover, oxaliplatin is known for its activity in gastrointestinal tumours with synergistic activity and a favourable toxicity profile when used in combination with 5-FU. Several studies using mFOLFOX for biliary tract tumours are available, with promising results and acceptable toxicity. The aim of this trial is to determine if patients (pts) with ABC benefit with respect to survival from the addition of mFOLFOX chemotherapy to ASC in the second-line setting after progression to first-line treatment with cisplatin and gemcitabine.

Trial design: This is a randomised phase III, multi-centre, controlled, open-label trial of pts with advanced biliary tract cancer with evidence of disease progression after prior cisplatin / gemcitabine chemotherapy treatment. Eligible pts (ECOG 0-1, adequate haematological, renal and liver function, adequate biliary drainage, with no evidence of ongoing infection) will be randomised (1:1) to receive either ASC (“standard” arm) or ASC with oxaliplatin/5-FU chemotherapy (“experimental” arm). The total number of participants planned is 162 (randomised 1:1). Randomisation and analysis will adjust for serum albumin levels, platinum sensitivity (determined from first-line therapy) and disease extent (locally advanced vs metastatic). The primary end point is overall survival. Quality of life and health economics assessments will be performed. Archival paraffin-embedded tissue will be collected at baseline and prospective blood samples will be collected for translational research. First patient was recruited on 27th March 2014; 4 pts have been randomized to date (6th May 2014) across 20 UK sites.

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