Capecitabine for resected biliary tract cancer

Indication	Post –operative treatment for completely resected advanced biliary tract cancer including gall bladder and cholangiocarcinoma
Treatment Intent	Adjuvant
Frequency and number of cycles	Every 21 days for 8 cycles
Monitoring parameters pre-treatment	• ECG prior to cycle 1 • **DPD testing:** It is highly recommended that DPD testing is undertaken before starting treatment; the result must be checked before treatment is started. • Monitor LFT's, U&E's and FBC at each cycle. • If neuts 1.0-1.4 and/ or Plts 75-100 d/w consultant. • If neuts <1.0 or PLT <75 delay and discuss with consultant. • **Renal impairment:** C+G should be used to measure renal function prior to each cycle. If CrCl < 50 ml/min dose reduce capecitabine (see SPC). Contraindicated if CrCl < 30ml/min. • **Interrupt capecitabine** in the event of ≥ grade 2 non-haematological toxicity (with the exception of side effects such as alopecia, alteration in taste etc, considered to be not serious) until resolution of toxicity to grade 0-1. • Consider dose reduction if grade 3 or 4 non-haematological toxicity OR repeat appearance of grade 2 (except N&V and alopecia). Delay until resolution of toxicity to ≤ grade 1 • **Cardiotoxicity**: Caution in patients with prior history of coronary heart disease, arrhythmias and angina pectoris. • **Skin reactions:** Capecitabine can induce severe skin reactions such as Stevens-Johnson syndrome and Toxic Epidermal Necrolysis. Patients should be informed of the possibility of such reactions and informed to seek urgent medical advice should any symptoms of a severe skin reaction occur. Treatment should be permanently discontinued in affected patients. • **Drug interactions**: Capecitabine must not be given with concurrent sorivudine or derivatives (e.g brivudine), see SPC. Monitor PT and INR regularly in patients taking coumarin-derivative anticoagulants. Monitor phenytoin levels with concomitant use. Caution with folinic acid or folic acid – potential for increased toxicity. Avoid concomitant allopurinol.
Reference(s)	St Lukes cancer alliance protocol v1 2017 EMC SPC accessed 01/10/2018 Adjuvant capecitabine for biliary tract cancer: The BILCAP randomized study 2017. Journal of Clinical Oncology 35, no. 15_suppl (May 20 2017) 4006-4006. K&M SACT proforma COL-003 v3 Jan 14

NB For funding information, refer to the SACT funding spreadsheet

Repeat every 21 days

Day	Drug	Dose	Route	Administration Details
1	**CAPECITABINE**	**(2500mg/m²/day) in 2 divided doses**	PO	**for 14 days** (the 1st dose will be taken as the evening dose on day 1 and the last dose is taken the morning of day 15, followed by a 7 day rest period) Take within 30 minutes after food, and approximately every 12 hours **Available as 500mg and 150mg tablets**
TTO	Drug	Dose	Route	Directions
	Metoclopramide	10mg	PO	up to 3 times a day as required. Do not take for more than 5 days continuously.

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Protocol No	UGI-059	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.	
Version	V1	Written by	M.Archer
Supersedes version	New protocol	Checked by	C.Waters E.Parry
Date	17/12/18	Authorising consultant (usually NOG Chair)	T.Sevitt