Peri-operative chemotherapy or surveillance in upper tract urothelial cancer (POUT - CRUK/11/027) - a randomised controlled trial to define standard post-operative management

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INTRODUCTION & OBJECTIVES: The POUT trial aims to establish whether platinum-based combination chemotherapy is superior to surveillance following nephro-ureterectomy with curative intent for upper tract transitional cell carcinoma (utTCC). POUT opened to recruitment in the UK on 31/05/2012, with the aim to randomise 345 participants world-wide over a 5-year period. The trial incorporates an initial 2 year recruitment optimisation phase, with qualitative research exploring issues relating to the recruitment process and targets relating to patient recruitment and the number of centres open. Initial milestones are: 9 centres open within 6 months of first centre opening, 18 centres open within first 12 months, and 22 patients recruited within the first 12 months.

MATERIAL & METHODS: Previous trials of adjuvant chemotherapy for urothelial cancers suggest that potential challenges to recruitment include randomisation between “no treatment” vs chemotherapy with its potential toxicity, and early identification of eligible patients. To ensure trial design was pragmatic and consistent with current practice we conducted a survey of participating UK centres. Prior to regulatory submissions a dedicated patient focus group with those who had experience of utTCC met to ensure the trial was relevant to patients and to further develop patient documentation.

RESULTS: 31 of 53 responding UK centres routinely place utTCC patients on surveillance following nephro-ureterectomy; 22 give chemotherapy if the patient is considered fit enough. The 13 respondents who specified chemotherapy regimens give gemcitabine and cisplatin or carboplatin, dependent on renal function. All centres discuss patients pre-operatively in a multi-disciplinary team meeting, but 7 centres do not routinely discuss patients post-operatively. The patient group welcomed the opportunity for utTCC patients to participate in research. They approved of the proposed randomisation between surveillance and chemotherapy and supported the use of a two stage pre- and

post-operative information giving process. Initial milestones relating to number of sites have been reached within 4 months of opening the trial and accrual is currently on target to meet the initial recruitment milestone.

CONCLUSIONS: There is no consensus among UK clinicians regarding optimum post-operative treatment of muscle invasive utTCC. The POUT trial offers the opportunity to standardise post-operative management of utTCC internationally and is supported by urologists, oncologists and patient representatives from the target population. To optimise clinical impact and deliver overall target recruitment within timelines, international recruitment is planned. An initial POUT European collaborators meeting will be held at the 28th Annual EAU Congress, for further information contact POUT-icrctsu@icr.ac.uk.