

## Kent and Medway SACT Protocol

### Paclitaxel & Gemcitabine for Metastatic Urothelial Cancer

Indication	Second or subsequent line treatment in advanced or metastatic urothelial cancer		
Treatment Intent	Palliative		
Funding approval required	No		
Drugs / Doses / Administration	<p><b>Day 1</b>  <b>Paclitaxel 135mg/m<sup>2</sup></b> iv infusion over 3 hrs in sodium chloride 0.9% 500ml (non-PVC bag) via in-line 0.22 micron filter. (If dose &lt;150mg, 250ml Sodium chloride 0.9%)  <b>Gemcitabine 1000mg/m<sup>2</sup></b> iv infusion in 500ml- 1000ml 0.9% sodium chloride over 30 minutes ( infusion duration may require adjustment for volumes &gt;500ml) Final concentration range 0.1mg/ml – 5mg/ml.</p> <p><b>Day 8</b>  <b>Gemcitabine 1000mg/m<sup>2</sup></b> iv infusion in 500ml- 1000ml 0.9% sodium chloride over 30 minutes (Infusion duration may require adjustment for volumes &gt;500ml). Final concentration range 0.1mg/ml – 5mg/ml.</p> <p><b>NB Cap BSA at 2m<sup>2</sup></b></p>		
Frequency and number of cycles	Every 21 days for up to 6 cycles		
Emetogenic potential (follow K&M guidelines for the management of SACT induced nausea and vomiting)	<p><b>Day 1:</b> Moderate  Pre-Chemo: Metoclopramide 20mg IV  N.B. Dexamethasone included as part of pre-med</p> <p>TTOs: Dexamethasone 6mg po om for 3 days after day 1 and metoclopramide 10mg po up to 3 times a day for 3 days, then 10mg up to 3 times a day as required after days 1 and 8 (do not take for more than 5 days continuously). Maximum 30mg metoclopramide per day including any pre-chemo dose.</p> <p><b>Day 8:</b> Minimal  Pre-chemo: Metoclopramide 20mg po</p>		
Pre-medication (if required) Drugs / doses / administration	<p><b>Day 1:</b>  Dexamethasone</p> <p>Chlorphenamine</p>	<p>12mg iv bolus</p> <p>10mg iv bolus through the side of a fast running Sodium Chloride 0.9% intravenous infusion.</p>	<p>30 minutes prior to paclitaxel</p>
Hydration (if required, follow K&M cisplatin hydration guidelines if appropriate)	None		
Monitoring parameters pre-treatment	<ul style="list-style-type: none"> <li>• Monitor FBC (day 1 and 8) and U&amp;Es/ LFTs (day 1).</li> <li>• If neuts 1.0-1.4 and PLT <math>\geq</math>100 d/w consultant.</li> <li>• If neuts &lt;1.0 or PLT &lt;100 defer 1 week or omit day 8.</li> <li>• Impaired renal and liver function d/w consultant.</li> <li>• Dose reduce Paclitaxel by 20% in the event of <math>\geq</math> grade 2 neuropathy and consider delay until recovery to <math>\leq</math> grade 1</li> <li>• Consider omitting paclitaxel in event of recurrent <math>\geq</math> grade 3 neuropathy or recurrent OR persistent <math>\geq</math> grade 2 neuropathy following a dose reduction.</li> <li>• Patients developing hypersensitivity reactions to Paclitaxel may be rechallenged with full dose Paclitaxel following prophylactic medication (e.g. famotidine 40mg po given 4 hours prior to treatment plus Hydrocortisone 100mg iv and chlorphenamine 10mg iv 30 minutes prior to treatment), then give paclitaxel over 3-6 hours (i.e. starting at over 6 hours and gradually increase rate if possible).</li> <li>• Dose reduction should be considered if any other grade 3 or 4 non-haematological toxicity or repeat appearance of grade 2 (except N&amp;V and alopecia). Delay until resolution of toxicity to <math>\leq</math> grade 1</li> </ul>		

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Post treatment observation (if required)	None
Additional TTOs	None (anti-emetics only)
Reference(s)	St Lukes Cancer Alliance Chemotherapy protocols Aria chemotherapy regimen BRE-014 Paclitaxel & Gemcitabine v 3.0 Changes made in line with SOP for removal of ranitidine on KMCC protocols and on aria regimens
Comments	BSA to be capped at 2.0m <sup>2</sup>

### Document Control

Protocol No:	URO-030	New protocol / Reason for update New protocol Changes made to V2 in line with SOP-005
Version:	2 Final	
Supersedes version:	1	
Date:	28.09.21	
Authorising consultant (usually NOG Chair)	C Thomas (V1)	
Written by:	S Wade (V1) M Archer (V2)	
Checked by:	C Waters (V1) / B Willis (V1)	

### Protocol build in Aria

Built by:	
Validated by (pharmacist):	
Validated by (consultant):	
Validated by (nurse):	

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