Clinical Trials Summary for out of hours Important Reference

Lancashire Teaching Hospitals NHS Foundation Trust

Acronym study title	A phase III, single-arm study to evaluate the efficacy and safety of ONCOFID-P-B (paclitaxel-hyaluronic acid conjugate) administered intravesically to patients with BCG-unresponsive Carcinoma in Situ of the bladder with or without Ta-T1 papillary disease (ORION trial)
Study Details	This study aims to investigate paclitaxel/hyaluronic acid administered to the bladder via catheter for carcinoma in situ of the bladder. The drug will be delivered in the **Lancashire Clinical Research Facility** by Urology trained nurses. This helpline number is provided to the patients as they are receiving chemotherapy and may develop adverse events related to this. However, as they are patients under the care of the Urology team, it is agreed that this team (PI if possible) should be made aware if patients ring this line unwell and certainly if they require admission with Urological issues.
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Drug therapy	Paclitaxel/Hyaluronic acid delivered intravesically into the bladder via catheter.
In the event that a patient calls this hotline for advise	In previous trials the adverse events experienced have been, with the vast majority mild to moderate intensity: UTI Fever Overactive bladder/Dysuria Haematuria Hypotension Bradycardia Atrial Fibrillation Pneumonia Diarrhoea

	Oral Parathesia Rash As this is administered intravesically, the likelihood of systemic chemotherapy adverse events is thought to be low. It has been agreed that if patients contact the helpline with chemotherapy related adverse events that are manageable this can be done via helpline (Paclitaxel guidance), and please alert the Urology research team aswell for their information. If patients have likely Urological issues (eg haematuria) then please alert the Research team or on-call Urology team if out of hours. The Urology team should then contact the PI Mr Smolski. Many thanks. Trial notes are kept in the medical notes and EVOLVE system for reference. Please advise patients to keep their trial documentation on their person when attending hospital for review.