Clinical Trials Summary for out of hours Important Reference

Lancashire Teaching Hospitals NHS Foundation Trust

Acronym study title	**Keynote 992 (MK3475-992)**
Study Details	A Phase 3, Randomized, Double-blind, Placebo-controlled Clinical Trial to Study the Efficacy and Safety of Pembrolizumab (MK-3475) in Combination With Chemoradiotherapy (CRT) versus CRT Alone in Participants with Muscle-invasive Bladder Cancer (MIBC) (KEYNOTE-992)
Principal Investigator PI Sub PI's	Dr Omi Parikh Dr Natalie Charnley
Research Nurse Team	Amanda Cook
Drug therapy	See table below
In the event that a patient calls this hotline for advise	Refer to SoC protocol for additional information regarding SoC treatment. Advise patient to seek medical assistance via nearest available healthcare provider depending upon severity of symptoms. Advise patient to keep all relevant trial paperwork with them for review by treating clinician. Patients requiring admission may be reviewed by the on-call Oncology SpR/Consultant. Day time contact number: Principal Investigator: Omi Parikh Tel: Tel: 01772 52 4574 / 3191 (Sec) Research Nurse: Amanda Cook Tel:01772 52 8475 If out of hours escalation is required, please alert PI/Co-I on the above details. Treatment interruption/modification may be required.

Drug	Dose/Potency	Dose Frequency	Route of Administration	Regimen/ Treatment Period	Use
pembrolizumab (MK-3475) [a]	400 mg	Q6W	IV infusion	Day 1 of each 6-week cycle, up to 9 cycles[a]	Experimental
placebo	Normal saline or 5% dextrose	Q6W	IV infusion	Day 1 of each 6-week cycle, up to 9 cycles[a]	Placebo
Option 1: Cisplatin[b]	35 mg/m^2	Per protocol regimen	IV infusion	Once weekly concurrent with RT	Treatment of cancer
Option 2: Gemcitabine[b]	27 mg/m^2	Per protocol regimen	IV infusion	Twice weekly concurrent with RT	Treatment of cancer
Option 3: 5-FU+MMC[b]	500 mg/m^2 + 12 mg/m^2	Per protocol regimen	IV infusion	Day 1-5 and Day 22-26 on Cycle 1 only for 5-FU and Day 1 on Cycle 1 only for MMC	Treatment of cancer