Clinical Trials Summary for out of hours Important Reference

NHS
Lancashire Teaching Hospitals
NHS Foundation Trust

Acronym study title	MK-5684-U01: A Phase 1/2 Platform Study to Evaluate the Safety and Efficacy of MK-5684-based Investigational Treatments in Participants With Prostate Cancer.
Study Details	This open-label study offers the trial drug (MK-5684) to patients with metastatic, castration resistant prostate cancer. This is either as a monotherapy or in combination with Olaparib or Cabazitaxel.
Principal Investigator PI Sub PI's	PI: Oncology consultant Dr Omi Parikh (Omi.Parikh@lthtr.nhs.uk) Sub-I: Dr David Cameron (David.Cameron@lthtr.nhs.uk)
Research Nurse Team	CRF Lead: Jacqueline Bramley (Jacqueline.Bramley@lthtr.nhs.uk)
Drug therapy	**MK-5684: This drug (previously named ODM-208) is an oral tablet.** Adverse event profile: The drug interferes with steroid synthesis. As such, patients are at risk of adrenal insufficiency or adrenal crisis (dizziness, hypotension, headache, abdominal pain). Management guidelines are provided in the study protocol and can be managed as per standard practice in the emergency setting. **Steroid supplementation: Dexamethasone and Fludrocortisone.** Adverse event profile: Cushing's syndrome, electrolyte disturbance, thin skin, easy bruising **Olaparib: PARP inhibitor, given as an oral tablet.** Adverse event profile: Reduced appetite, altered taste sensation, headache, dizziness, nausea, vomiting, diarrhoea, dyspepsia, stomatitis, upper abdominal pain, fatigue, anaemia, neutropenia, thrombocytopenia Myelodysplastic syndrome/Acute myeloid leukaemia: < 1.5% Pneumonitis, including events with a fatal outcome, has been reported in <1.0% [Taken from LSC Cancer Network guidelines 2023] **Cabazitaxel: IV Chemotherapy.** Adverse event profile: Hypersensitivity reaction Neutropenia, anaemia, thrombocytopaenia Nausea, Vomiting Diarrhoea, Dehydration, Cardiac arrhythmias, Haematuria, Fatigue, Pyrexia [Taken from LSC Cancer guidelines 2020]
In the event that a patient calls this hotline for advise	Advise patients to seek urgent medical attention if they are unwell. Patients should keep all trial related paperwork to present to treating medical teams upon arrival.

	During working hours teams can contact the PI on the above email address or Clinical Research Team on 01772 522031. Patients are provided with an emergency kit containing oral and IM hydrocortisone. They are educated on how to administer this kit at home if required if there is a concern of adrenal crisis.