Clinical Trials Summary for out of hours Important Reference

Lancashire Teaching Hospitals NHS Foundation Trust

Acronym study title	**Amplitude Study**
Study Details	A Phase 3 Randomized, Placebo-controlled, Double-blind Study of Niraparib in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for the Treatment of Participants with Deleterious Germline or Somatic Homologous Recombination Repair (HRR) Gene-Mutated Metastatic Castration-Sensitive Prostate Cancer (mCSPC)
Principal Investigator PI Sub PI's	**PI – Dr Omi Parikh** **Sub Investigator - Dr Alison Birtle/Dr Natalie Charnley**
Research Nurse Team	**Research Nurse - Catherine Walmsley** **CTSO - Zainab Chauhan**
Drug therapy	**TREATMENT GROUPS AND DURATION** Participants will be randomized on a 1:1 basis to 1 of 2 treatments groups: niraparib 200 mg, AA 1000 mg, and prednisone 5 mg daily AA 1000 mg and prednisone 5 mg daily All study medications will be administered orally once daily. Matching placebos will also be administered. All participants will receive ADT (ie, gonadotropin-releasing hormone analogue or surgical castration).
In the event that a patient calls this hotline for advise	- Seek medical advice from GP or A&E depending on severity of AE reported. - Inform study nurse and PI. - Advise patient to stop trial medication