(To be printed on local hospital headed paper)

TOPARP Part B

Trial of Olaparib in Patients with Advanced Castration Resistant Prostate Cancer.

PART B PHARMACKINETIC SUB-STUDY
PATIENT INFORMATION SHEET

TOPARP: Trial of Olaparib in Patients with Advanced Castration Resistant Prostate Cancer

We are inviting you to take part in an optional sub-study of the TOPARP trial

- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide if you wish to take part.
- You are free to decide if you want to take part in this research study. If you choose not to take part, this will not affect the care you get from your own doctors in any way.
- You can decide to stop taking part in the study at any time without giving a reason.

1 Pharmacokinetics

Pharmacokinetic studies are undertaken to investigate what a person's body does to a drug once it has been administered. Pharmacokinetics looks at the absorption, distribution, metabolism and excretion of a drug within the body and the onset, intensity and duration of its effects. Pharmacokinetic properties of drugs may be affected by aspects such as where the drug is given and the dose. The results of pharmacokinetic studies can be useful in determining the appropriate use of a medicine and for the design and conduct of further clinical trials.

The TOPARP Part B Pharmacokinetic sub-study will be undertaken on Cycle 1 Day 8 (during trial treatment) only. Blood samples (2ml - just less than a teaspoon) will be taken before you take Olaparib and then 30mins, 1 hour, 1 hour 30 minutes, 2 hours, 4 hours, 6 hours, 8 hours and 12 hours after taking the drug.

These eight blood samples will be sent, without any identifiable personal information, to an external laboratory, where they will used to determine the concentration of Olaparib in your blood at each time point.

2 Side effects associated with study procedures

Sometimes a bruise and/or swelling can arise where the needle is inserted. As with any wound, an infection can also develop at the injection site. See your doctor if the wound site becomes red and inflamed.

The sub study involves taking bloods at varying time points over a period of over 12 hours. You will be allowed to eat and drink during these twelve hours. After the last blood sample is taken, you will be allowed to go home, as no overnight hospital stay will be necessary.

How to contact us

If you have any questions about this study, please talk to your doctor at
Hospital Department
Hospital
Address
Address
Tel: 01234 XXX XXX