**What should I be aware of?**

* You may have some days where you feel unwell whilst receiving your radiotherapy with or without additional chemotherapy. Radiotherapy treatment with or without chemotherapy can cause unpleasant side effects. We have listed some/the most likely ones of these in your Patient Information Sheet. Your research nurse and doctors will ask you about any symptoms you may have had so that we can keep a record of them and try to help reduce/ease them. We will provide telephone support if you have any specific concerns relating to your treatment programme and contact details for out of hours will be provided to you prior to starting treatments.
* Maintaining confidentially during the study is of the utmost importance to us, and the information collected about you will be handled strictly in accordance with the information on the Consent Form, and the Data Protection Act 2018.

Decision to enter the trial

**2 in 3** people

**1 in 3** people

• • • • • approx. 1 month • • • •

 6

months

 12

 months

 9 months

 24

months

Start of treatment

3

months

7.5 weeks

…

End of treatment

Chosen at Random

Hospital follow-up appointments

Higher Dose Radiotherapy

Standard Dose Radiotherapy

Hospital follow-up appointments

Once daily

Mon-Fri

for 28 days

Trial

End

Trial End



Leeds Institute of Clinical Trials Research Unit

APHRODITE Key Facts Sheet, version 2.0, 24th March 2022

*IRAS ID: 250957*

 

**A Phase II trial of Higher RadiOtherapy Dose In The Eradication of early rectal cancer**

**KEY FACTS SHEET**

 Sponsored by: Funded by:

 

APHRODITE Key Facts Sheet, version 2.0, 24th March 2022

*IRAS ID: 250957*

**On the study**

* Once you start the study, we will treat your cancer with radiotherapy and chemotherapy over 5 1/2 weeks (Monday to Friday, with your weekends free). The chemotherapy can either be in tablet form, or injected directly into your vein. Alternatively, if your doctor does not feel that you are suitable to receive chemotherapy, then you may be treated with radiotherapy alone.
* At the beginning and end of your treatment we would like you to complete 3 questionnaires on your quality of life. We would also like you to complete them on your follow up appointments at 3, 6, 9, 12 and 24 months. Your research nurse will provide the questionnaires for completion on the day of your visit. It would be helpful to us if these are completed in clinic before you see your doctor at your hospital visit, so please arrive a little earlier before your appointment to complete the questionnaires. Alternatively, the questionnaires can be completed after your appointment with your doctor. Once completed you can hand the questionnaires to the doctor or research nurse.
* We will keep checking that you are OK during the study and will carry out regular blood tests that check your full blood count, liver function and kidney function. We will also ask how well you are or if you are having any side effects during your treatment to monitor your progress.

**Once your treatment finishes**

* We would like to continue to monitor your progress once your treatment has ended. We will arrange a telephone appointment for you with your research nurse 2 weeks after you finish your radiotherapy. From then on you will have regular follow up appointments at the hospital with your doctor at 3, 6, 9, 12 and 24 months following the start of your treatment. Your doctor may choose to have you back more often, if they think it will be better for you.

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**What is the APHRODITE study?**

* We would like a total of 104 volunteers who have early rectal (back passage) cancer to take part in a study called APHRODITE.
* Patients with your type of cancer would normally undergo surgery to remove their rectum. However, some patients are unable to undergo surgery and others would prefer to try and avoid surgery. Within the APHRODITE trial such patients are offered treatment using radiotherapy (strong x-ray treatment) plus chemotherapy (drugs) to try and kill all their cancers cells and cure their cancer.
* This study wants to find out if a higher dose (amount) of the radiotherapy is better than a standard dose and if it can improve the chance of the cancer disappearing quicker and aid recovery.
* In this study you will be randomised to either the higher or the standard radiotherapy dose group. ‘Randomised’ means that a computer will select at random which group you go in to.
* We need to randomise all of our volunteers so that we get the best quality results about the chemotherapy and radiotherapy we are treating you with. Two thirds of volunteers will get the higher dose and one third the standard dose.

**What is involved? - Before you enter**

* Before you enter the study, you will need to sign a Consent Form. This will be given to you by your doctor, with a Patient Information Sheet that will contain all the information you need to know about the study.
* Please take as much time as you need to look at all the information and ask your Doctor or Research Nurse any questions you may have about the study before deciding to take part. It is completely your own decision whether to enter into this study.
* If you do decide to enter, then you and your doctor will go through your Consent Form together.