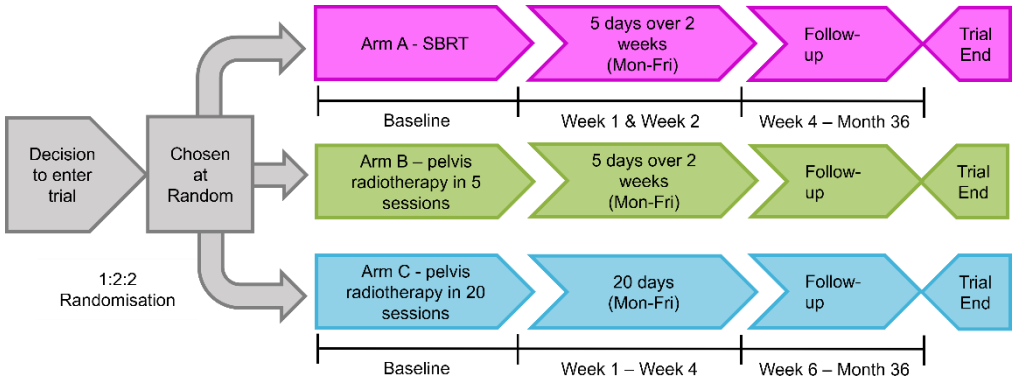
What should I be aware of?

- You may have some days where you feel unwell whilst receiving your radiotherapy and hormone therapy. Radiotherapy treatment can sometimes cause unpleasant side effects. We have listed some of the most likely ones of these in your Participant 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.



Leeds Institute of Clinical Trials Research Unit

ctru

POINTER-PC

Pelvis Or Involved Node Treatment: Eradicating Recurrence in Prostate Cancer (POINTER-PC)

KEY FACTS SHEET

Sponsored by:

UNIVERSITY OF LEEDS

Funded by:

Yorkshire Cancer Research

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On the study

- Once you start the study, we will treat your cancer with radiotherapy on every other day for 2 weeks if receiving 5 treatments of pelvis radiotherapy or SBRT, or daily for 4 weeks if receiving 20 treatments of pelvis radiotherapy.
- At the beginning (before your radiotherapy treatment) we would like you to complete a questionnaire on your quality of life. We would also like you to complete this on your follow up appointments at 2 weeks, and at 3, 6, 12, 24 and 36 months. You will be provided with the questionnaires in your requested format (electronic or paper).
- We will keep checking that you are OK during the study and will carry out regular blood tests, including asking about any side effects that you might have and checking your prostate-specific antigen (PSA) blood test.
- If you have consented for the blood sample collection, these will be taken before treatment, at the end of radiotherapy and 3 months after finishing radiotherapy.

Once your treatment finishes

- We would like to continue to monitor your progress once your treatment has ended. From then on you will have regular follow up appointments with your doctor at 2 weeks, 6 weeks, and 3, 6, 12, 18, 24, 30 and 36 months following the end of your treatment.
- Your doctor may choose to review you more often, if they think it will be better for you. After 3 years, you will be reviewed by your doctor as often as they feel appropriate and at least annually.

What is the POINTER-PC study?

- We would like a total of 480 volunteers with recurrent prostate cancer to take part in a study called POINTER-PC.
- Participants with your cancer are typically treated with surgery or radiotherapy. When this cancer comes back in the glands (known as lymph nodes) in the pelvis, there are different treatments that could be used but we do not know for certain which treatment is best. The POINTER-PC study is trying to work this out.
- Two different types of radiotherapy could be used. The gland(s) could be treated with focused radiotherapy given in a small number of treatments (5 treatments), which is called stereotactic body radiotherapy (SBRT). Or, both the surrounding pelvis as well as the gland(s) known to be cancerous could be treated with radiotherapy, which is known as pelvis radiotherapy. Pelvis radiotherapy might be better than SBRT at stopping the cancer coming back again in the pelvis or in another part of the body.
- POINTER-PC will compare pelvis radiotherapy with SBRT to see which is better at stopping the cancer from coming back again.
- In this study all volunteers will be randomised, with half receiving SBRT in 5 treatments, a quarter pelvic radiotherapy in 5 treatments and a quarter pelvic radiotherapy in 20 treatments.

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 Participant Information Sheet that contains information that 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 if you have any questions about the study before deciding to take part. It is completely your own decision whether to enter this study.
- If you do decide to enter, then you and your doctor will go through your Consent Form together.
- There is also an optional blood sample collection and optional tissue sample collection as part of the study, which we will use to try to improve treatment for future patients.

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