

Informed Consent Form (Bengali Language)

MRI-guided focal boost in radiation therapy for prostate cancer

This is a clinical trial, which is a type of research. Your study doctor will explain this clinical trial to you. Only people who want to take part in a clinical trial are included in the trial. Please take your time to decide whether to take part. You can discuss your decision with your friends and family. You can also discuss it with your healthcare team. If you have any questions, you can ask your study doctor for further explanation.

You are being asked to take part in this study because you have prostate cancer and your doctor has recommended external beam radiation therapy.

1. Why is this research being done?

Advances in radiotherapy for prostate cancer have shown that applying high doses to cancer nodules within the prostate increases the chances of curing prostate cancer and effectively halves its recurrence rate.

With advanced technology, it is possible to provide high doses of treatment without increasing long-term side effects.

This radiotherapy technique is being used around the world, including at Tata Medical Centre. In this study, we are evaluating the results of this new treatment on prostate cancer patients undergoing treatment at Tata Medical Centre.

2. How many people will participate in this study?

Approximately 120 people will participate in this study.

3. What happens if I participate in this study?

Before starting the study...

You will need to have the following tests, examinations or procedures before radiotherapy. These tests, examinations or procedures are part of routine cancer treatment and will be done even if you do not take part in this study.If you have had some of these recently, some tests may not need to be repeated.

- Medical history and physical examination.
- A cancer biopsy will be performed to confirm the malignant nature of your tumor. In the case of an external pathology report, your doctor will review. You will be asked to submit the slides for. The pathologists of our institute.
- A multi-parametric MRI to identify the main intraprostate lesion and PSMA-PET to help determine the stage of the disease.

- Blood tests: Complete blood count, blood electrolytes, kidney, liver, and thyroid function tests.
- IPSS Scoring
- Documentation of pre-treatment urinary and rectal symptoms and quality of life.

During the research...

If the tests and procedures suggest that you may be eligible for this study and you are willing to participate, you will need to undergo the following assessments. These are part of routine cancer treatment.

- Quality of life assessment using the QLQC30 and PR25 EORTC questionnaires at the beginning and end of treatment.
- All side effects of treatment — regardless of study participation — will be assessed once a week as part of routine clinical evaluation for all patients.

You will be given conventional radiotherapy. Depending on the stage of your disease, this radiotherapy treatment will be given either in a total of twenty sessions, five days a week over four weeks, or in five sessions once a week using IMRT and image-guidance. Each radiation session will take 20-30 minutes.

When your radiation treatment is over...

You will need these tests and procedures:

- Quality of life was assessed at the beginning, end of treatment, and every 3-6 months thereafter using the QLQC30 and PR25 EORTC questionnaires.
- All patients, regardless of study participation, will be monitored for all side-effects of treatment as part of regular clinical evaluation – 6 weeks after radiotherapy (RT) and then at each routine follow-up visit every 3-6 months.
- Clinical assessment of the disease will be performed at each follow-up visit through serum PSA testing and physical examination.

4. How long will I be in the study?

In the conventional treatment of prostate cancer, patients are evaluated every 3-6 months for 5 years and then once a year for at least 10 years. In this study, you will be evaluated in the same manner and for the same period of time. The only additional study-related task will be to complete a quality of life assessment form at each visit.

5. Can I stop being in the study?

Yes. You can decide to stop at any time. If you are thinking about stopping or decide to stop, tell the study doctor. He or she will tell you how to do this. If you stop participating in the study, you will no longer be asked to complete the quality of life assessment form. All other normal follow-up activities will continue.

6. What side effects or risks might I experience as a result of participating in this study?

These side effects are a part of conventional radiation therapy for prostate cancer, whether you participate in this study or not. Everyone who participates in the study will be carefully monitored for any side effects.

Possible risks and side effects related to radiation include the following:

Possible early/short-term side effects of radiotherapy for prostate cancer:

- **Expected side effects (50%–100%)** These include fatigue, frequent urination, sudden urge to urinate, and a slower rate of urination than usual.
- **Common side effects (10-50%)** These include frequent bowel movements (having to pass stools more often than usual) and a sudden, strong urge to defecate, soft stools containing more mucus or gas than usual.
- **Rare side effects (<10%)** These include skin irritation and discoloration at the treated area), pain during urination due to inflammation of the bladder or cystitis, pain or discomfort in the anus due to inflammation of the rectum, a feeling that the stomach is not completely emptying, or mild bleeding from the bladder or intestines.
- **Rare side effects (<1%)** These include urinary retention – the inability to urinate, which may require the insertion of a urinary catheter, and urinary incontinence, which includes leaking urine.

Delayed side effects of radiotherapy and hormone therapy for prostate cancer:

- **Expected side effects (50%–100%)** Include impotence caused by hormone therapy and/or radiotherapy.
- **Common side effects (10-50%)** These include frequent urination (urinating more often than usual) and urgency (urgent need to urinate or defecate soon), changes in semen – such as decreased volume, dryness, changes in consistency or blood, inability to orgasm, changes in penis length or appearance, inability to get an erection.
- **Rare side effects (<10%)** These include incomplete bladder emptying or decreased bladder capacity, urethral stricture (a narrowing of the urethra, sometimes requiring surgery), frequent defecation (having to pass stool more often than usual), bleeding from the bladder or intestines, and occasional abdominal discomfort.
- **Rare side effects (<1%)** These include urinary incontinence, including urine leakage (1%), thinning and/or fractures of the pelvic/hip bones, damage to the bowel/bladder that may require surgery – perforation (hole), fistula (abnormal connection between two parts of your body), intestinal obstruction (blockage) or severe bleeding, and an increased risk of different types of cancer at the site of treatment.

Talk to your research doctor for more information about risks and side effects.

7. Why should I participate in this study?

Your participation in this study will help your treatment team learn about disease control, side effects, and quality of life in patients treated with MRI-guided focal boost radiation therapy for prostate cancer. This information may benefit many patients in the future.

8. If I do not participate in this study, what other options do I have?

Whether you participate in this study or not is entirely your decision. Your treatment plan will not change as a result of participating in the study.

9. Will my medical information be kept confidential?

We will do our best to keep the personal information in your medical records confidential. However, your personal information may be disclosed if legally required. If the information obtained from this study is published or presented at a scientific conference, your name and other personal information will not be used.

10. What is the cost of participating in this study?

If you agree to take part in this study, you will be responsible for the normal cost of radiotherapy required for the treatment of your prostate cancer. You will not be charged any additional money. You will not be paid for taking part in this study.

11. What happens if I get injured as a result of participating in this study?

This study only periodically evaluates the results and side effects of a conventional treatment. You will not be harmed as a result of these evaluations.

12. What are my rights if I participate in this study?

Your participation in this study is voluntary. You may or may not participate in this study. If you decide to participate in this study, you may leave the study at any time. Regardless of your decision, you will not be penalized and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You will continue to receive your medical care from our institution.

We will inform you about any new information or changes in the study that may affect your health or your willingness to continue the study.

13. Who can answer my questions about the research?

If you have any questions or concerns about this study, you can talk to your study doctor. Call Tata Medical Center to learn about your rights while participating in this study. Institutional Review Board (a group that reviews research to protect your rights)

Contact us	Email	Phone	Address
Dr. Indranil Mallick	indranil.mallick@tmckolkata.com	০৩৩ ৬৬০৫ ৭৪০২/৭৪০৬	Tata Medical Centre, Kolkata
Institutional Review Board	irb@tmckolkata.com	০৩৩ ৬৬০৫ ৮১৪৬	Tata Medical Centre, Kolkata

14. Consent

I have read or had read to me the information stated in the Informed Consent Document provided for this study. <u>MRI-guided focal boost in radiation therapy for prostate cancer.</u>	<input type="checkbox"/>
I have received an explanation of the nature, purpose, duration, possible effects and risks of this test, and what is expected of me. My questions have been answered satisfactorily.	<input type="checkbox"/>
I understand that my participation in this trial is voluntary and that I may refuse to participate or withdraw from the trial at any time without penalty or loss of benefits to which I am entitled.	<input type="checkbox"/>
I also understand that I will be informed if any information is found during the research that may affect my willingness to participate.	<input type="checkbox"/>
The Institutional Review Board may request to review my medical records to verify the information collected. By signing this document, I am giving permission for this review of my records.	<input type="checkbox"/>
I understand that my identity will not be disclosed in any report or publication.	<input type="checkbox"/>
I agree to participate in the above research.	<input type="checkbox"/>

Subject name

Signature/Fingerprint

Date

Name of legal relationship

Signature

Date

Name of impartial witness

Name/Signature of the person giving consent