

MRI-guided Focal Boost in Prostate Cancer Radiation Therapy

Informed Consent Document

MRI-guided Focal Boost in Prostate Cancer Radiation Therapy

This is a clinical trial, which is a type of research study. Your study doctor will explain the clinical trial to you.

Clinical trials include only people who choose to take part. Please take your time to decide whether to participate. You may discuss your decision with your friends and family. You may also discuss it with your health care team. If you have any questions, you can ask your study doctor for more information.

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

I. Why is this study being done?

Advances in prostate cancer radiotherapy have shown that giving a higher dose to cancer nodules within the prostate increases the chances of curing prostate cancer and reduces the recurrence rate by about half.

With advanced technology, high-dose treatment can be given without increasing long-term side effects.

This radiotherapy technique is being implemented around the world, including at Tata Medical Center. In this study, we are evaluating the outcomes of this new treatment in prostate cancer patients treated at Tata Medical Center.

II. How many people will take part in the study?

About 120 people will take part in this study.

III. What will happen if I take part in this research study?

Before you begin the study...

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

- Medical history and physical examination
- Biopsy to confirm the cancer. If there is an outside pathology report, you will need to submit the slides for review by the pathologists of our institute

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- Multi-parametric MRI of the prostate and PSMA-PET to assist in staging the disease
- Blood tests: complete blood count, electrolytes, kidney, liver, and thyroid function tests
- IPSS scoring
- Documentation of pre-treatment urinary and rectal symptoms and quality of life

During the study...

If the tests show that you can be included in the study and you choose to participate, the following assessments will be done:

- Quality of life assessment using the QLQC30 and PR25 EORTC questionnaire at the start and end of treatment
 - All treatment side effects, assessed once every week as part of routine clinical evaluation for all patients

You will receive the current standard radiotherapy treatment.

This will be given either as twenty treatments, five days a week for four weeks, or as five treatments once a week, using IMRT and image guidance, depending on your disease stage.

Each radiation session will take 20–30 minutes.

When your radiation treatment is completed...

You will need the following tests and procedures:

- Quality of life assessment at baseline, at the end of treatment, and then every 3–6 months using the QLQC30 and PR25 EORTC questionnaire
 - All treatment side effects as part of routine clinical assessment for all patients, regardless of participation in the study, at 6 weeks after radiotherapy and then every 3–6 months at each standard follow-up visit
 - Clinical evaluation of the disease at each follow-up visit with serum PSA and clinical examination

IV. How long will I be in the study?

In the standard treatment practice for prostate cancer, patients are assessed every 3–6 months for 5 years, and then once a year for at least 10 years. In this study, you will be assessed in the same pattern and for the same duration.

The only additional study-related activity will be filling out a quality of life assessment form at each visit.

V. Can I stop being in the study?

Yes. You may decide to stop at any time. Inform the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to do this.

If you stop participating in the study, you will no longer be asked to fill out the quality of life assessment forms. All other standard follow-up activities will continue.

VI. What side effects or risks can I expect from being in the study?

These side effects are part of standard radiation therapy for prostate cancer, regardless of your participation in the study. Everyone taking part in the study will be watched carefully for any side effects.

Foreseeable risks and side effects related to radiation include:

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

- Expected side effects (50%–100%) include tiredness, urinary frequency (passing urine more often than normal), urgency (sudden urge to pass urine), and slower flow than normal
 - Common side effects (10%–50%) include bowel frequency (opening your bowels more often than normal), urgency (sudden urge to open your bowels), looser stools with more mucus or wind than normal
 - Less common side effects (<10%) include skin irritation and colour changes in the treatment area, cystitis/pain while urinating due to bladder inflammation, rectal pain/discomfort due to rectal inflammation, a feeling of not completely emptying the bowels, or mild bleeding from the bladder or bowel
 - Rare side effects (<1%) include urinary retention, meaning inability to pass urine which may require a urinary catheter, and urinary incontinence, including leakage of urine

Late side effects of radiotherapy and hormonal therapy for prostate cancer:

- Expected side effects (50%–100%) include impotence due to hormonal therapy and/or radiotherapy
 - Common side effects (10%–50%) include urinary daytime/night-time frequency, urgency, changes in ejaculate such as reduced amount, dry, altered consistency, or blood-stained ejaculate, loss of orgasm, change in penile length/appearance, and inability to achieve an erection
 - Less common side effects (<10%) include incomplete emptying of the bladder or reduced bladder capacity, urinary stricture (narrowing in the urine passage which occasionally requires surgery), bowel frequency, bleeding from the bladder or bowel, and intermittent abdominal discomfort
 - Rare side effects (<1%) include urinary incontinence, pelvis/hip bone thinning and/or fractures, bowel/bladder damage which may require surgery due to perforation (hole), fistula

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(abnormal connection between two parts of the body), bowel obstruction, or severe bleeding, and an increased risk of a different cancer in the treatment area

For more information about risks and side effects, ask your study doctor.

VII. Why should I take part in the study?

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

VIII. What other choices do I have if I do not take part in this study?

It is your choice whether or not to be part of this study. Your treatment plan will not change based on your participation in the study.

IX. Will my medical information be kept private?

We will do our best to ensure that the personal information in your medical record is kept private. However, your personal information may be disclosed if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

X. What are the costs of taking part in this study?

If you choose to take part in this study, you will pay the standard costs for the radiotherapy required to treat your prostate cancer. You will not be charged any additional amount. You will also not be paid for taking part in this study.

XI. What happens if I am injured because I took part in this study?

The study involves only periodic assessments of outcomes and side effects of a standard-of-care treatment. These assessments will not cause any injury to you.

XII. What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time.

No matter what decision you make, there will be no penalty and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still receive your medical care from our institution.

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

XIII. Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study.

For questions about your rights while taking part in this study, call the Tata Medical Center Institutional Review Board, which is a group of people who review research to protect your rights.

Contact information:

Dr. Indranil Mallick — indranil.mallick@tmckolkata.com — 033 6605 7402/7406 — Tata Medical Center, Kolkata

Institutional Review Board — irb@tmckolkata.com — 033 6605 8146 — Tata Medical Center, Kolkata

XIV. Consent

I have read, or have had read to me, the information given in the Informed Consent Document for this study entitled MRI-guided Focal Boost in Prostate Cancer Radiation Therapy.

☐ I have received an explanation of the nature, purpose, duration, and foreseeable effects and risks of the trial, and what I will be expected to do. My questions have been answered satisfactorily.

☐ I understand that my participation in the trial is voluntary and that I may refuse to participate or may withdraw from the trial at any time, without penalty or loss of benefits to which I am otherwise entitled.

☐ I further understand that any information that becomes available during the course of the study that may affect my willingness to take part will be informed to me.

☐ Institutional review board authorities may wish to examine my medical records to verify the

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information collected. By signing this document, I give permission for this review of my records.

- ☐ I understand that my identity will not be revealed in any report or publication.
- ☐ I agree to take part in the above study.

Name of Subject

Signature/thumb impression

Date

Name of Legal Relation

Signature

Date

Name of the Impartial Witness

Name of the person/Signature of the person administering consent