

## **Informed Consent Document (English Language)**

### **MRI-guided Focal Boost in Prostate Cancer Radiation Therapy**

This is a clinical trial, 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 make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more 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.

#### **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 improves chances of curing prostate cancer and effectively halves the rate of recurrence.

With advanced technology, the higher dose treatment can be delivered without increasing long term side-effects.

This technique of radiotherapy is being implemented across 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 have the following exams, tests or procedures before radiotherapy. These exams, tests or procedures are part of regular 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.

- History and physical examination.
- A biopsy of your cancer to confirm the malignant nature of your tumour. In case of an outside pathological report, your doctor will require you to submit the slides for review by pathologists of our institute.
- A multi-parametric MRI of the prostate to identify the dominant intraprostatic lesion and PSMA-PET to assist in staging the disease
- Blood investigations Complete Blood count, Blood electrolytes, Renal Liver and Thyroid function tests.

- IPSS scoring
- Documentation of pre-treatment urinary and rectal symptoms and quality of life.

**During the study ...**

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following assessments. They are part of regular cancer care.

- Quality of life assessment using the QLQC30 and PR25 EORTC Questionnaire at the start and end of treatment
- All the side-effects from the treatment. - assessed once a week as a part of routine clinical assessment for all patients regardless of their participation in the study.

You will receive the current standard treatment of radiotherapy. Radiotherapy treatment either with twenty treatments five days a week for four weeks or with five treatments once a week using IMRT and image-guidance, depending on your disease stage. Each radiation treatment will take 20-30 minutes.

**When you are finished receiving radiation...**

You will need these tests and procedures:

- Quality of life assessment at baseline, end of treatment and 3-6 monthly thereafter using the QLQC30 and PR25 EORTC Questionnaire
- All the side-effects from the treatment as part of routine clinical assessment for all patients regardless of their participation in the study - at 6 weeks post RT and then every 3-6 months at each standard follow up visit as a part of routine clinical assessment
- Clinical evaluation of the disease will be done at each follow up visit with a serum PSA and clinical examination.

**IV. How long will I be in the study?**

In the standard practice of treatment of 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 involve filling up a quality of life assessment form at each visit.

**V. Can I stop being in the study?**

Yes. You can decide to stop at any time. Tell 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 study participation you will no longer be asked to fill up 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 you may face are a 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 the radiation include those which are:

### 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 compared to normal.
- **Common side effects (10-50%)** include bowel frequency (opening your bowels more often than normal) and urgency (sudden urge to open your bowels), looser stools with more mucous or wind compared to normal.
- **Less common side effects (<10%)** include skin irritation and colour changes in treatment area), cystitis/pain when you urinate – due to bladder inflammation, rectal pain/discomfort – due to rectal inflammation, a feeling of not completely emptying your bowels, or mild bleeding from your bladder or bowel.
- **Rare side effects (<1%)** include urinary retention – not being able to pass urine which may result in needing a urinary catheter, urinary incontinence including urine leaking.

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

- **Expected side effects (50%–100%)** include impotence from the hormonal therapy and/or radiotherapy .
- **Common side effects (10-50%)** include urinary daytime/night-time frequency (passing urine more often than normal) and urgency (the urge to pass urine or stool soon)), changes in ejaculate – such as reduced amount, dry, altered consistency or blood stained, loss of orgasm, change to penile length/appearance, inability to achieve an erection.
- **Less common side effects (<10%)** include incomplete emptying of your bladder or reduced bladder capacity, urinary stricture (a narrowing in your water pipe which occasionally requires surgery), bowel frequency (opening your bowels more often than normal), bleeding from your bladder or bowel, intermittent abdominal discomfort.
- **Rare side effects (<1%)** include urinary incontinence including urine leaking (1%), pelvis/hip bone thinning and/or fractures, bowel/bladder damage which may require surgery – due to perforation (hole), fistula (abnormal connection between two parts of your body), bowel

obstruction (blockage) or severe bleeding, 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 find out 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 a 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 make sure that the personal information in your medical record will be kept private. However, your personal information may be given out 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 be paying the standard costs for radiotherapy that you require for treating 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 the 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 to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about 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 (a group of people who review the research to protect your rights)

Contact	E-mail	Phone	Address
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

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I have read or have had read to me the information given in the Informed Consent Document for this study entitled <b><u>MRI-guided Focal Boost in Prostate Cancer Radiation Therapy.</u></b>	<input type="checkbox"/>
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.	<input type="checkbox"/>
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.	<input type="checkbox"/>
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.	<input type="checkbox"/>
Institutional review board authorities may wish to examine my medical records to verify the information collected. By signing this document, I give permission for this review of my records.	<input type="checkbox"/>
I understand that my identity will not be revealed in any report or publication.	<input type="checkbox"/>
I agree to take part in the above study.	<input type="checkbox"/>

**Name of Subject**

**Signature/thumb impression**

**Date**

**Name of Legal Relation**

**Signature**

**Date**

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**Name of the Impartial Witness**

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**Name of the person/Signature of the person administering consent**