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Title of Study: A Prospective Evaluation of Multi-Parametric Magnetic Resonance Imaging (mpMRI) Guided Stereotactic Body Radiation Treatment for Localized Prostate Cancer

Sponsor: Departmental Funding

RUSH

Subject Information Sheet and Consent Form

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

Why are you being invited to participate in this study?

You are being asked to take part in this study because you have prostate cancer that has not spread beyond the prostate.

What is the purpose of this study?

A type of imaging called multi-parametric magnetic resonance imaging (mpMRI) has been approved to detect aggressive, high-grade, invasive prostate cancer. This is considered the standard care for prostate cancer. An MRI is a type of scan that uses magnets, radio waves, and a computer to produce images of body structures. The purpose of this study is to evaluate the effects, good and/or bad, of using mpMRI to guide high-dose radiation treatment for prostate cancer.

How many study subjects are expected to take part in the study?

Approximately 134 subjects (67 subjects in each cohort) are expected to take part in this study at Rush University Medical Center.

What will you be asked to do?

Before you begin the study …

You will need to have the following exams, tests or procedures to find out if you can be in the

study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- History and physical exam, including a digital rectal exam (DRE) and an assessment of your ability to carry out activities of daily living (which will include questions such as whether you are able to feed, bathe, and dress yourself)
- A biopsy (removal of a sample of tissue) of your prostate to determine your Gleason score (a value that helps determine the stage of your prostate cancer).
- A blood test to determine your PSA (a value that helps determine the stage of your prostate cancer). About 2 teaspoons of blood will be drawn from a vein or, if you have one, a catheter (plastic tube for vein access). Your study doctor also may check your testosterone level.
- mpMRI to determine which treatment group you will be registered (assigned) to
- A bone scan to determine if the cancer has spread to the bones (group 2 and some subjects in group 1).
- A CT (computed tomography) scan of your pelvis to determine if the cancer has spread to any pelvic lymph nodes (group 2 and some subjects in group 1). (A CT scan is a 3-dimensional X-ray view of the inside of your body. The study doctor may order a "contrast agent" a special type of dye administered to you.)

During the study …

If the exams, tests and procedures show that you can be in the study, and you choose to take part, you will be "registered" into one of the study groups described below based on the results of mpMRI.

If you are in group 1 (often called "Cohort 1") because your mpMRI is negative (no tumor found in the series of special images), you will receive radiation therapy two days a week over two and a half weeks, for a total of 5 treatments.

If you are in group 2 (often called "Cohort 2"), you will receive radiation therapy once daily, 5 days a week, Monday through Friday, for a total of 25 treatments for the first 5 weeks, this is followed by additional 3 treatments over one and a half weeks.

In both groups, you will be asked to drink 16-24 ounces of water or other fluid 2-3 hours prior to treatment and to not urinate between this time and treatment as you are able.
You will also be advised to adhere to a low gas, low motility diet beginning one day prior to the treatment. One tablespoon of Milk of Magnesia (a common laxative to reduce constipation) can be taken the night before the simulation and the night before each treatment. One Fleet's enema will be administered 2-3 hours before the simulation and each treatment.

Your first radiation therapy appointment is called a simulation. The simulation appointment is used to plan your treatment and does not involve an actual treatment. Your team will use imaging scans, such as a computed tomography (CT) scan, to plan your treatment making sure the radiation beam targets your tumor.

After the simulation, your team will review your information and design a treatment plan. Sophisticated computer software helps the team develop this plan. Your doctor will then write a

prescription about the course of your radiation treatment.

After registration, you will need the following tests and procedures. They are part of regular cancer care.

- History and physical exam, including an assessment of your ability to carry out activities of daily living *(Weekly during radiation treatment)*

You will need this assessment to see how the study treatment is affecting your body.

- Assessment of any side effects you may be experiencing from the treatment *(Weekly during radiation treatment)*

When you are finished receiving radiation…

You will need these tests and procedures every 6 months for the first 2 years following the start of radiation, every 6 months for years 3, 4, and 5, and then annually:

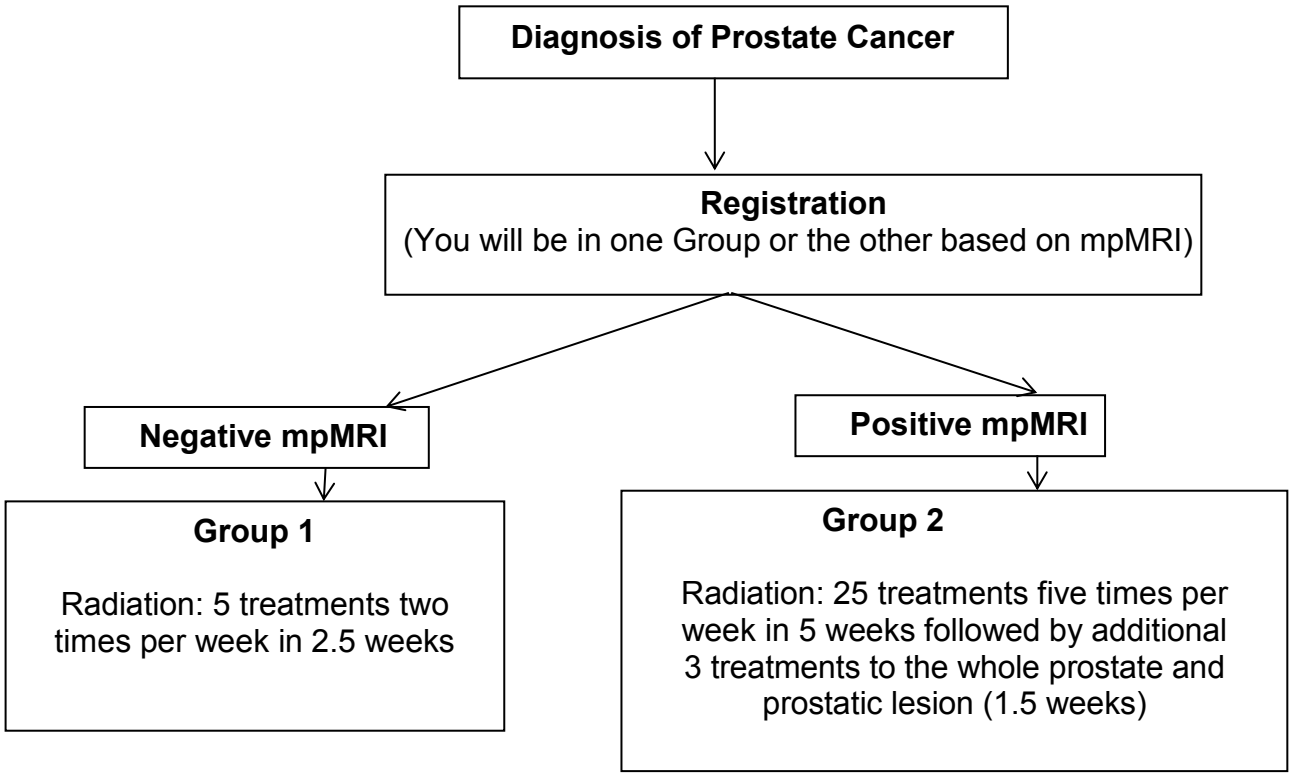
- History and physical exam, including a digital rectal exam (DRE) and an assessment of your ability to carry out activities of daily living
- A blood test to determine your PSA (a value that helps determine the stage of your prostate cancer).
- Assessment of any side effects you may be experiencing from the treatment

You will need these tests and procedures also:

- If your doctor suspects your cancer is growing after treatment (progression), s/he may request a needle biopsy of your prostate to check your response to treatment.

Study Plan

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



How long will you be in the study?

You will receive radiation treatments of either 5 treatments over two and a half weeks or 28 treatments over six and a half weeks. After you are finished receiving radiation, the study doctor will ask you to visit the office for follow-up exams every 6 months for the first 2 years following the start of radiation, then every 6 months for the years 3, 4, and 5. After that, the study doctors would like to keep track of your medical condition by seeing you for follow-up exams every year.

You may be removed from this study without your consent. Possible reasons may be that the study doctor decides that continued participation in the study will be harmful to you, you will need a treatment not allowed on the study, your disease becomes worse, you are unable to take the treatment as directed, or the study is canceled.

What are the possible risks of the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects are temporary (occur for a short period) and go away soon after you stop radiation treatment. In some cases, side effects can be serious, long lasting, or may never go away. Side effects that last a longer time or may never go away are often referred to as chronic. In addition, some of the side effects may be life threatening and, in rare instances, may cause death.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects related to the radiation include those which are:

Likely

- Tanning, redness, or darkening of skin in treatment area
- Rash, itching or peeling of skin
- Temporary hair loss in the treatment area
- Temporary fatigue (feeling tired), nausea or diarrhea
- Abdominal cramps
- Bladder irritation with a stinging sensation (the stinging sensation usually occurs while passing urine)
- Frequency or urgency of urination
- Rectal irritation with more frequent bowel movements
- Mild rectal bleeding that does not require treatment

Less Likely

- Urinary obstruction (blockage) requiring the placement of a temporary urinary catheter
- Inability to achieve an erection (inability of the penis to become hard)
- Chronic bowel/bladder symptoms as described above under "Likely"

Rare but Serious

- Injury to the bladder, urethra, bowel, or other tissues in the pelvis or abdomen. Rarely, ulcers may develop in the bladder, urethra, or bowel.
- Intestinal obstruction (this results in blockage of the bowel and may require surgery)
- Rectal bleeding that requires medication or surgery to stop the bleeding

Blood draw risks: You may experience pain or discomfort, and/or bleeding, and bruising at the site the needle enters the body, and in rare cases, fainting or infection.

CT scan risks: CT scans will be used to assess the spread of your disease. The total radiation exposure from these tests is considered small and is not likely to affect you or your disease in a negative way, but can add up over time. The contrast solution (a dye that is injected to get a clearer picture) that may be given for a CT scan or MRI may cause an allergic reaction (rare). The CT contrast solution can cause kidney damage, especially if you are diabetic, dehydrated, or elderly. When the contrast dye is injected during the CT scan, you may experience nausea, flushing, warmth, or a salty taste.

MRI scan risks: In MRI scans (including the mpMRI), you will be required to lie in a narrow tube, which may make you feel uncomfortable or claustrophobic. The MRI makes loud banging noises. You will be given earplugs if you would like them. If you are feeling uncomfortable, this study can be stopped at any time at your request. Also, if you have very poor kidney function, the contrast material could cause a rare, but serious skin disorder that may result in large areas of hardened skin. You should not have a MRI if you have a pacemaker, or metal plate in your body.

Are there any anticipated pregnancy risks?

You are responsible for using an effective birth control methods with your partner, such as birth control pills, barrier method (such as condoms or diaphragms), intrauterine device (IUD), hormone implants or surgical sterility while you are taking part in this study. If you are a male and your female partner becomes pregnant, you must notify your study doctor immediately. Once you have completed treatment, you may discontinue birth control after 3 months**.**

Are there benefits to taking part in the study?

There may be no direct benefit to you for participating in this study**.** We do know that the information from this study will help researchers learn more about these different doses as a treatment for prostate cancer. This information could help future patients with prostate cancer.

What other options are there?

Instead of participating in this study, you may choose another form of treatment such as:

- Getting treatment or care for your cancer without being in a study; this could include the following options, either alone or in combination with each other:
  - Current standard radiation therapy over 8-9 week course five days a week
  - External (three-dimensional or non–three-dimensional) radiation therapy
  - Internal radiation using permanent radioactive seeds implanted in the prostate or brachytherapy. Brachytherapy uses very tiny plastic catheters (small tubes) placed in the prostate to deliver temporary radioactive seeds that are removed after treatment.
  - Three-dimensional radiation therapy or IMRT (intensity-modulated radiation therapy) similar to the therapy described in this study
  - Surgery

  - Hormone therapy
- Taking part in another study
- Getting no treatment (with this choice, your tumor could continue to grow and your disease could spread)

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. You will be assigned an identification number that will replace your name and any identifying information in all study documents.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people

If you withdraw from this study, the data already collected from may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Your identity will not be revealed on any report, publication, or at scientific meetings.
In order to conduct the study, the study doctor, Dr. Dian Wang, will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctor will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

A description of this clinical trial will be available on http://www.CLINICALTRIALS.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What are the costs of your participation in this study?

All costs that are part of your usual medical care, such as history and physical with digital rectal exam, prostate biopsy, PSA and testosterone blood tests, bone scans, CT of pelvis, and mpMRI, will be charged to you or your insurance company. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this research study.

Will you be compensated or paid?

You will not be paid for taking part in this study.

Your participation in this research study may contribute to the development of commercial products from which the Sponsor or others may derive economic benefit. You will have no rights to any products, patents or discoveries arising from this research, and you will receive no economic benefit.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of your participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: **Dian Wang, MD 312-942-9397**. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT:

Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

☐ *Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

SIGNATURE BY WITNESS/TRANSLATOR
(for use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily.

Signature of Witness/Translator	Date of Signature

☐ Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature

☐ Check here if Principal Investigator obtained consent and a separate signature is not required.