THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

A prospective pilot study investigating rhPSMA 7.3 PET/MRI in detecting recurrent disease and aid in radiotherapy planning in patients with biochemically recurrent prostate cancer post prostatectomy

2020-1347

Study Chair: Dr. Devaki Shilpa Surasi

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

STUDY SUMMARY

You are being asked to take part in this study because you have had previous surgery for prostate cancer and it is now suspected that the prostate cancer may have come back based on levels of prostate-specific antigen (PSA) in your blood. However, an increase in PSA levels alone does not tell the doctor where the cancer may be or how much cancer there may be. Imaging tests, like a bone scan, magnetic resonance imaging (MRI), and/or computed tomography (CT), are often performed to help the doctor learn where or how much cancer there is, and how best to treat the cancer.

rhPSMA-7.3 (^{18}F) is a radioactive tracer agent that is being studied for use in PET/MRI imaging to help diagnose and look for the spread of prostate cancer. Prostate-specific membrane antigen (PSMA) is a protein that is expressed in prostate cancer and this agent targets the PSMA molecule.

The goal of this clinical research study is to learn if using rhPSMA-7.3 (^{18}F) during PET scans (along with MRIs performed during the same scan) can help the doctor better find where the cancer may be spreading and how much of it there is. The results of this study may also guide in radiation treatment planning.

This is an investigational study. The radiotracer (rhPSMA-7.3 (^{18}F)) used in this study is not FDA approved or commercially available. It is currently being used for research

purposes only. The study doctor can explain how the radiotracer is designed to work in more detail.

The radiotracer used together with a PET/MRI scan may help detect sites where the cancer may have spread. The results from the PET/MRI scan will not be the only diagnostic information used to plan your prostate cancer care because the usefulness of the radiotracer has not yet been proven. Future patients may benefit from what is learned. There may be no benefits for you in this study.

If you have a tissue biopsy (described below), possible risks include: pain, bleeding, infection, and damage to the surrounding tissues or structures. There is also a risk that, during the biopsy, the study doctor cannot collect enough tissue and the sample cannot be used to make a diagnosis. You will be asked to sign a separate consent that explains the procedure.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. You can read a full list of potential side effects below in the Possible Risks section of this consent.

The exact length of your participation could vary depending on the results of the PET/MRI scan. If the scan is negative, your participation will last for up to a week after the scan to complete follow up. If the scan is positive for disease, a follow-up PET/MRI scan will be performed 6 months after starting hormonal therapy or 3 months after the end of radiation therapy to check the response to treatment. After the second scan, your participation would then last for up to an additional week to complete the follow up.

The research rhPSMA-7.3 (^{18}F) PET/MRI scans will be provided at no cost to you while taking part in this study.

You may choose not to take part in this study. Instead of taking part in this study, you may choose other diagnostic methods. Your doctor can discuss the available methods to you. In all cases, you will receive appropriate medical care. If you decide not to take part in this study, it will not affect your treatment options.

1. STUDY DETAILS

Screening Visit

Signing this consent form does not mean that you will be able to take part in this study. To help the doctor decide if you are eligible, you will be asked about your medical history, including a history of when prostate cancer was first diagnosed, previous prostate cancer treatment details, the types and results of other imaging tests (such as MRIs, PET scans, and CT scans) performed. You will also be asked about any medications you are currently taking.

If the screening questions show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

Up to 25 participants will be enrolled in this study. All will take part at MD Anderson.

Imaging Visit 1
If you are found to be eligible to take part in this study, on the day of your scheduled first PET/MRI scan, the study staff will place a catheter into a vein in your arm. A catheter is a sterile flexible tube that will be placed into a large vein. Your doctor will explain this procedure to you in more detail, and you will be required to sign a separate consent form.

Before having the PET/MRI scan, you will receive 2 injections. The first injection will be the radiotracer (rhPSMA-7.3 (^{18}F)) which is injected through the catheter and will be given over about 2 minutes. You will then wait 50-90 minutes after the radiotracer is given before starting the PET/MRI scan.

During the scan, you will lie on your back on the scanning bed, preferably with your arms rested above your head. The second injection, which will be the MRI contrast agent, will be given during the scan. The contrast agent helps the doctors “see” inside the body. The scan usually takes up to 60 minutes.

Follow-Up Visit 1
On the day of and within 7 days after the PET/MRI scan, you will called and asked about any side effects or changes in your health that you may have had since your last visit and any changes to or new medications you are taking. This call should last about 5 minutes.

Your imaging results will be discussed with you by your treating doctor. If the doctor thinks it is needed because the research imaging scans provided different results than the standard of care imaging, further tests/procedures (such as a tissue biopsy) will be done to confirm the location and extent of the disease shown on the PET/MRI scan image. A tissue biopsy will only be done if it is safe to do so and will be used to determine if your treatment plan should be changed. This will be considered part of your standard of care, if needed, and discussed with you.

Because the radiotracer is investigational, it is possible that the PET/MRI scan results are not accurate. For example, the PET/MRI scan may show there is a lesion or tumor but in reality, does not exist.

Imaging Visit 2
If there is evidence of rhPSMA disease in the first PET/MRI scan, about 6 months after starting hormonal therapy or 3 months after the end of radiation therapy you will return to the clinic for a second PET/MRI. You will repeat the same procedures described above at “Imaging Visit 1.”

Follow-Up Visit 2
On the day of and within 7 days after the second PET/MRI scan, you will contacted to be asked about any side effects or changes in your health that you may have had since

your last visit and any changes to or new medications you are taking. This call should last about 5 minutes.

Your participation in this study will be over after Follow-Up Visit 2.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The known side effects are listed in this form, but they will vary from person to person.

You will be exposed to radiation from the radiotracer (**rhPSMA-7.3 (^{18}F)**). The level of radioactivity you are exposed to during this study is the same as the background radiation you would be exposed to as part of your daily life over about 2 years. The radioactive solution does not stay in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system. The main risk of all radiation exposure is the possibility of developing a radiation-induced cancer later in life. At these exposure levels, the risk is small.

rhPSMA 7.3 (F18) may also cause a feeling of warmth or pain at the injection site. It may cause headache and dizziness. It may cause an allergic reaction, which may cause breathing and/or skin problems (rash, redness, blisters, itching, and/or swelling). Side effects can happen right away or within a few days after the injection. It may cause anaphylactic shock (a severe allergic reaction that can cause breathing difficulty and/or a drop in blood pressure).

During the **PET**/**MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the PET/MRI staff and the scanning will be stopped if you wish. During the scan, MRI contrast agent will be administered. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site. The tissue or surrounding area may be damaged. An allergic reaction to the anesthetic may occur. A scar may form at the site.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
Taking part in this study can result in risks to an unborn baby, so you should not father a child while on this study. You should not have sexual intercourse for at least 24 hours after receiving the radiotracer. You must also agree to use effective birth control and not to donate sperm for 3 months after each injection of radiotracer is given.

Talk to the study doctor about appropriate methods of birth control. Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Confidentiality Risk: Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or Blue Earth Diagnostics for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Devaki Shilpa Surasi, at 713-792-6536 or by email at DSSurasi@mdanderson.org) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Blue Earth Diagnostics, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, including the results of all of your standard tests performed as part of this research, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is sponsored and/or supported by: Blue Earth Diagnostics.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers,

and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

Conflict of Interest

Dr. Brian Chapin (Collaborator) has received compensation from Blue Earth Diagnostics as a Consultant. The financial interests are within the limits of the conflict of interest policy.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Blue Earth Diagnostics, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   The results of this study may be published in a medical journal and shown at medical meetings. You will not be identified (by name or any other means, such as photographs) in any of these publications. PET/MRI images may be shared with medical professionals and/or with Blue Earth Diagnostics.

   Please note that you have the right to view and access your personal data and to ask for correction as allowed by law. If you wish to make a request, then please contact the study doctor, who can help you contact the sponsor, if needed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2020-1347**.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION