COVER PAGE

The Role of 68Ga-PSMA-11 PET in Surgery Guidance in Prostate Cancer: A prospective Pilot trial

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

NCT04936334

29 MARCH 2022

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

The Role of ^{68}Ga-PSMA-11 PET in Surgery Guidance in Prostate Cancer: A prospective Pilot trial

You are invited to participate in a research study of an investigational type of PET scan, which will be compared to post-surgical tissue analysis, to see if this scan will be helpful in detecting prostate cancer and guiding surgical treatment. You are being selected as a possible subject because of your diagnosis of prostate cancer. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Clinton Bahler, M.D. of the Indiana University Department of Urology, Mark Green, Ph.D., and Mark Tann, M.D., of the Indiana University School of Medicine Department of Radiology and Imaging Sciences. It is funded by the American Cancer Society.

STUDY PURPOSE

The purpose of this study is to evaluate a radiopharmaceutical (a radioactive imaging agent) called ^{68}Ga- PSMA-11. This imaging agent seeks to identify prostate cancer based on its expression of a specific protein target, prostate-specific membrane antigen (PSMA), which is known to be present at high levels on the surface of most prostate cancer cells. The tests will involve using ^{68}Ga-PSMA-11 positron emission tomography (PET) scan of your body to look for evidence of tumor locations. This scan may provide your surgeon with additional information about your cancer's location that may help guide the surgeon as they attempt to preserve muscle and nerve tissue near your prostate while also attempting to remove all of your cancer. The post-surgical analysis is focused on comparing the pre-surgery PET images with pathology images of the removed cancer. Specifically, this study will look at how well the pre-surgery PET scan predicts the local spread of prostate cancer beyond prostate boundaries. The study also tracks quality-of-life before and after the surgery.

The ^{68}Ga-PSMA-11 radiopharmaceutical is investigational, which means it has not yet been approved by the Food and Drug Administration (FDA). However, it has been used for prostate cancer imaging in hundreds of prior patients at Indiana University, and thousands of patients worldwide. The results of the ^{68}Ga-PSMA-11 scan will be considered in combination with your standard-of-care data such as biopsy pathology and MRI imaging.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, you will be one of 55 subjects who will be participating in this research.

PROCEDURES FOR THE STUDY

If you agree to be in the study, you will do the following things:

You will be screened to ensure you meet all inclusion and exclusion criteria. Your medical history will be taken. You will be asked to complete baseline quality of life assessments focusing on erectile function, urinary function and overall mental and physical health. You must be diagnosed with prostate cancer with plan for standard of care prostate removal at Indiana University.

You will receive a single intravenous injection of the ^{68}Ga-PSMA-11 radiopharmaceutical, followed by a PET/CT scan. The results of this scan will be discussed with you.

The PET scan is expected to be performed using a combined PET/CT camera. The research PET imaging will occur as a separate visit from your standard-of-care prostate imaging. The PET scan involves the following steps:

a. An intravenous tube, or line, will be placed in one of your arm veins to allow for injection of the radioactive substance.
b. You will be asked to empty your bladder. On returning to the injection room, the 68Ga-PSMA-11 radiopharmaceutical will be injected via the intravenous tube, followed by flushing of that tube with sterile saline solution.
c. Approximately 5-minutes after the radiopharmaceutical injection you will be asked to lie down on your back on a platform on the PET/CT scanner. The scanner will collect PET images which will require about 45-minutes.
d. The intravenous line will be removed, and you will be allowed to leave the imaging facility.

You will be monitored while at the imaging site to observe for any adverse events. All study procedures will take place at IU Health facilities.

After your surgery, you will continue to follow up with your physician per standard of care prostate cancer follow up. At each of these follow up visits in the first year post-surgery (1 month, 3 months, 6 months, 12 months), you will be asked to complete the same quality of life assessments as prior to your surgery.

You will be in this study for approximately two years.

RISKS OF TAKING PART IN THE STUDY

While on the study, the risks are:

1. Loss of confidentiality. During this study, we will collect information about your medical condition and the results of the scans. To minimize the risk that your medical information might be seen by persons who are not involved in the study, our files are kept in a secure area. Also, your name will never appear in any research reports. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law (such as when the FDA asks to review our files).

2. Radiopharmaceutical Administration and PET/MR. The amount of this radioactive imaging agent is so small that you should not experience any drug effects whatsoever. In the very rare event this occurs (similar to an allergic reaction), our personnel are trained to quickly recognize and treat it. Signs of an allergic reaction include: rash, itching, swelling, and shortness of breath. Possible risks from placing a tube in your arm vein include bruising, and rarely, infection. To minimize the risks, all procedures will be performed by certified nuclear medicine technologist trained to perform clinical PET imaging studies using sterile (very clean) procedures.

Your participation in this research study involves exposure to radiation in addition to what you may receive as part of your standard care. The benefit from the radiation you receive for your standard care typically outweighs the risk because it allows your doctor to provide appropriate medical care; however, the additional radiation "dose" you receive for research purposes may not benefit you personally. Regulatory agencies have established annual radiation dose limits for individuals who work with radiation (e.g. x-ray technologists, radiologists, etc.). If you decide to participate in this research study, the radiation dose you receive will not be above the annual limit for radiation workers.

Radiation has been shown to cause cancer and/or leukemia from doses that are higher than the additional annual radiation dose you will receive by participating in this study. According to the Health Physics Society (an international organization that specializes in radiation protection), the increased risk of health effects from the additional annual radiation exposures in the range of those you will receive while participating in this research study is either too small to be observed or nonexistent in the normal population. While there is no evidence that any risk exists for humans exposed to this amount, it is assumed that the risks rise with lifetime accumulated dose from all sources of ionizing radiation, including the doses you receive from medical procedures and the environment. You should also be

aware that everyone's sensitivity to radiation is not the same and some diseases (e.g. genetic diseases, diseases affecting DNA repair, and immune diseases such as HIV) may make you more sensitive to the effects and consequences of the radiation exposure than the normal population. Finally, you should know that even if there is an increased risk of an effect, it could be 5 to 20 years before any effect would actually occur. Thus, you may want to factor in your age, overall health, and the number of medical radiation procedures that you've had when determining if this risk is acceptable to you. The calculated effective dose resulting from your participation in this study is available upon request.

3. Since this is an investigational study there may be risks that are unknown or unforeseeable. Your participation could be terminated by the investigators at any time if significant acute or chronic medical, neurologic, or psychiatric illness in the subject that, in the judgment of the Principal Investigator, could compromise your ability to complete the study, and/or compromise the objectives of the study.

If you have had radiation (like x-rays, CT or radiation therapy) before or you participated in a different study where you were exposed to radiation, please tell us now. We want to make certain that the probability of harm from the amount of radiation you will be exposed to in this study continues to be low when combined with the radiation you have received within the past year.

The PET scans that you may get in this study will expose you to radiation. Every day, people are exposed to low levels of radiation that come from the natural environment and man-made radiation sources around them. This type of radiation is called "background radiation." The amount of radiation you will get from the scans in this study is approximately 3-4 years' worth of background radiation. Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. Certain diseases or conditions may affect your sensitivity to radiation. For more detailed information on the risks of radiation or if you wish to have a more detailed dose estimate, please ask your study doctor.

4. You may experience discomfort or uncomfortableness answering quality of life assessments related to this study. If you are uncomfortable answering questions for these assessments, please let the study nurse know. The study nurse or research coordinator will determine if these assessments are required for continuation in this study.

BENEFITS OF TAKING PART IN THE STUDY

Your ^{68}Ga-PSMA-11 scan may detect the location, extent, and characteristics of your cancer, allowing improved planning of your surgery. However, as this is an early phase study to learn how well ^{68}Ga-PSMA-11 images can assist in treatment planning, you are not guaranteed to directly benefit from being in the study. The results of the ^{68}Ga-PSMA-11 scan will be considered in combination with your standard-of-care data such as biopsy pathology and MRI imaging.

ALTERNATIVES TO TAKING PART IN THE STUDY

Instead of being in the study, you may choose not to participate and continue your regular cancer treatment, including the standard imaging scans. Medical care will not be withheld if you choose not to participate.

USE OF INFORMATION

- The following individuals and organizations may receive or use your identifiable health information:
- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University

  - The Indiana Clinical Research Center (ICRC)
- US or foreign governments or agencies as required by law
- Data safety monitoring boards and others authorized to monitor the conduct of the study
- The following research sponsors: American Cancer Society; its representatives or designees
- State or Federal agencies with research oversight responsibilities, including but not limited to:
  - The United States Food and Drug Administration (FDA)

CONFIDENTIALITY

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies.

A description of this clinical trial will be available on 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.

USE OF INFORMATION FOR RESEARCH IN THE FUTURE

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information which could identify you, such as your name and other identifiers, will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

COSTS

You will not be responsible for any research related costs related to the PSMA-PET scan. If this exam reveals significant and unexpected abnormalities, you and/or your insurer will be responsible for any clinically indicated tests to investigate these abnormalities. MRI imaging is standard-of-are and will be billed to your insurer in the same manner whether or not you choose to participate in this trial. Any treatment related costs (e.g. surgery) are not covered by this trial.

PAYMENT

You will receive no payment for participation in this research study.

COMPENSATION FOR INJURY

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. No money or funds are set aside to pay for these types of injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled by signing this Informed Consent form.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher, Dr. Bahler at 317-944-3458 (or for imaging issues, Dr. Mark Tann at (317-944-1800).

In the event of an emergency, you may contact the on-call physician at 317-944-5000.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose not to take part, or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University Health or the Departments of Urology or Radiology and Imaging Sciences, Indiana University School of Medicine.

If you want to stop being in the study, tell the study doctor or study staff. If you decide to stop being in the study, the study doctor or study staff may ask you some questions about when you were in the study. If you, or your study doctor, decide to stop your participation from the study you may be asked to return for follow-up visits to help monitor your health and condition.

During the course of the study, if we receive any important new information about the study, that might change your mind about continuing in the study, the study doctor or study staff will tell you about it. You are free to withdraw your consent from the study at any time. Your participation could be terminated by the investigators at any time if significant acute or chronic medical, neurologic, or psychiatric illness in you that, in the judgment of the Principal Investigator, could compromise your safety, limit your ability to complete the study, and/or compromise the objectives of the study.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject's Signature:_____**Date**:_____
(must be dated by the subject)

Subject's Printed Name:_____

Signature of Person Obtaining Consent:_____ _____**Date**:_____

Printed Name of Person Obtaining Consent:_____