22-003732

68Ga-PSMA-11 PET/CT for Screening Prior to 177Lu-PSMA-617 Therapy

NCT05547386

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MAYO CLINIC

Name and Clinic Number

Approval Date: **May 3, 2023**
Not to be used after: **May 2, 2024**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: ^{68}Ga-PSMA-11 PET/CT for Screening Prior to ^{177}Lu-PSMA-617 Therapy

IRB#: 22-003732

Principal Investigator: Dr. Geoffrey Johnson and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research study is to provide access to ^{68}Ga-PSMA-11 PET/CT imaging. You have been asked to take part in this research because you are being considered for ^{177}Lu-PSMA-617 treatment as part of your clinical care.
What's Involved	Study participation involves one ^{68}Ga-PSMA-11 PET/CT scan. You will be in the study until the completion of the ^{68}Ga-PSMA-11 PET/CT scan.
Key Information	There may not be a direct benefit to you by participating in this imaging study. If you take part in this research, you will have one ^{68}Ga-PSMA-11 PET/CT scan that involves exposure to radiation. The amount of

	radiation from the ^{68}Ga-PSMA-11 PET/CT scan has a low risk of harmful effects. The most common side effects of 68Ga-PSMA-11 were: • Nausea • Diarrhea • Dizziness The risks associated with study participation are completely described later in this form, be sure to review them carefully. This study will take approximately 2-3 hours to complete. As with all research, there is a chance that confidentiality could be compromised, however, we take precautions to minimize this risk and all other known risks. This study is being done to gather information and provide access to 68Ga-PSMA-11 PET/CT. You may choose not to take part in this study.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Geoffrey Johnson, MD, PhD **Phone:** 507-284-4104 **Study Team Contact:** Amber Stephan **Phone:** (507) 266-2927 **Institution Name and Address:** Mayo Clinic 200 First St SW Rochester MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
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.

Why are you being asked to take part in this research study?

You have been asked to take part in this research study because you are being considered for ^{177}Lu-PSMA-617 treatment as part of your clinical care.

Why is this research study being done?

The purpose of this research is to provide access to ^{68}Ga-PSMA-11 PET/CT imaging for patients being considered for ^{177}Lu-PSMA-617 treatment as part of their clinical care. There may be up to 250 participants in this study.

Combining a PET scan with a CT scan can help make the images easier to interpret. PET/CT scans are hybrid scanners that combine the two modalities into a single scan. This allows images of both anatomy (CT) and function (PET) to be taken during the same examination.

The ^{68}Ga-PSMA-11 PET/CT scan is done with a very small amount of a radioactive tracer called 68-Gallium PSMA-11. In patients that have been diagnosed with prostate cancer, a protein called prostate-specific membrane antigen (PSMA) appears in large amounts on the surface of the cancerous cells.

The radioactive imaging agent (^{68}Ga-PSMA-11) has been designed to circulate through the body and attach itself to the PSMA protein on prostate cancer cells. A PET/CT scan is then used to detect the location of prostate cancer lesions.

The specific formulation/version of ^{68}Ga-PSMA-11 used in this study is considered investigational, which means it either has not been approved by the FDA for routine clinical use or for the use described in this study. However, the FDA has allowed the use of this drug in this research study. We don't know all the ways that this drug may affect people, but we hope the information from this study will help us develop a better imaging study to diagnosis prostate cancer in the future.

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Information you should know

Who is Funding the Study?
Mayo Clinic is funding this study.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will be in the study until the completion of the ^{68}Ga-PSMA-11 PET/CT scan.

What will happen to you while you are in this research study?

The PET/CT scan will be done in the Charlton Building. This appointment will last approximately 2-3 hours, including reporting to the location where imaging will be performed 30 minutes prior to the time you will receive an intravenous (IV) injection of 68Ga-PSMA-11, 60 minutes of time to wait for ^{68}Ga-PSMA-11 to go to sites where cancer may be hiding in your body, and 30 minutes for the scanning in the PET/CT scanner. You do not have fast for this appointment.

You will be led to an uptake room where an intravenous catheter (IV) will be placed in a vein in your arm. This catheter will be used to inject ^{68}Ga-PSMA-11, a radioactive imaging agent designed to specifically attach itself to the PSMA protein on prostate cancer cells. After the imaging agent is injected, you will be asked to sit and relax quietly for approximately 60 minutes to allow the drug to circulate in your body.

Next, a technologist will lead you to the PET/CT scanner. You will be positioned on the scanner bed on your back with your hands above your head or at your sides. The technologist will then begin the 30-minute PET/CT scan. During this scan, it is important to stay as still as possible.

The scan report and images will be available in your medical record.

After the PET/CT scan, you will continue on with your routine clinical care as advised by your treating physician.

What are the possible risks or discomforts from being in this research study?

If you take part in this research, you will have one ^{68}Ga-PSMA-11 PET/CT scan that involve exposure to radiation. The amount of radiation from the ^{68}Ga-PSMA-11 PET/CT scan has a low risk of harmful effects.

The most common side effects of ^{68}Ga-PSMA-11 are:

- Nausea
- Diarrhea
- Dizziness

As with any medication, allergic reactions are a possibility. The risk of an allergic reaction to ^{68}Ga-PSMA is minimal. As with any new or investigational drug, there may be adverse events or side effects that are currently unknown and it is possible that certain unknown risks could be permanent, serious, or life-threatening.

The risks of intravenous (IV) line placement include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick. To minimize this risk, IV lines will be placed by experienced technologists.

As with all research, there is a chance that confidentiality could be compromised, however, we take precautions to minimize this risk and all other known risks.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator, the study sponsor, or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

New Information
During the study new information about the imaging agents may become available. If this happens, your doctor will tell you about any new information that could affect your decision to continue participating in the study. You may be asked to sign an updated consent form that contains the new information.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

What are the possible benefits from being in this research study?

This imaging study may not make your health better. However, having this scan may aid in meeting the criteria to be considered for ^{177}Lu-PSMA-617 treatment as part of your routine clinical care.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- ^{68}Ga-PSMA-11 administration
- ^{68}Ga-PSMA-11 PET/CT scan

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.

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How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. .In order to protect the confidentiality of your information, study data will be labeled with a unique identifying number (or "code"). Only the study staff at the site will have access to your personal information linking you to your study code, which will be stored in a secure location. If the results of the research are made public, information that identifies you will not be used.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

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You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at:researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature