17-008120

^{68}Ga-DOTATATE PET for Localization of Phosphaturic Mesenchymal Tumors in Patients with Tumor Induced Osteomalacia

NCT03736564

Document Date: 11/11/2022

MAYO CLINIC

Name and Clinic Number

Approval Date: **November 11, 2022**
Not to be used after: **June 9, 2023**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: ^{68}Ga-DOTATATE PET for Localization of Phosphaturic Mesenchymal Tumors in Patients with Tumor Induced Osteomalacia

IRB#: 17-008120

Principal Investigator: Matthew Drake, M.D., Ph.D. and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

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.

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 a copy of this form to keep. A copy of this form will be put in your medical record.

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Dr. Matthew Drake **Study Team Contacts:** Dr. Jad Sfeir Dr. Peter Tebben Dr. Stephen M. Broski	**Phone:** (507) 284-4738 **Phone:** (507) 284-2617 (507) 255-9085 (507) 284-4104 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Participant Advocate (The RPA is independent of the Study Team)	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study
Patient Account Services	**Toll-Free:** (844) 217-9591	▪ Billing or insurance related to this research study

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

You are being asked to take part in this research study because you have previously been diagnosed with low levels of phosphate in your blood caused by a condition called tumor induced osteomalacia and previous efforts to localize the hormonal source of your low phosphate level were unsuccessful.

The plan is to have about 22 people take part in this study.

It may be possible, at the discretion of the investigator, for you to participate in this study more than once if appropriate. The maximum number of times you may participate in this study is 2.

2. Why is this research study being done?

The purpose of this study is to evaluate a newer imaging technique (Ga-DOTATATE PET/CT) to see if it is more sensitive to localize the source of the hormone, which has caused the low phosphate levels.

3. Information you should know

Who is Funding the Study?
This study is being funded by the Division of Nuclear Medicine at Mayo Clinic.

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.

4. How long will you be in this research study?

You will be in the study until the PET/CT scan is obtained. Your medical records may be accessed for up to one year after completing the scan in order to collect additional clinical or follow-up information.

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

If you agree to be in this research study, you will be asked to visit with your healthcare provider at the Mayo Clinic in Rochester as part of the standard of care practice, and then undergo a PET/CT scan, as part of the research study, using Gallium-68 Dotatate, which is a radioactive imaging agent. When the results of the scan are available, they will be shared with your provider who will, in turn, share them with you. The provider may suggest scheduling additional visits or referrals, depending on the scan results, as part of the standard of care.

If you are female, you must have a negative pregnancy test within 48 hours prior to your PET/CT scan in order to participate in this study, unless you cannot become pregnant.

You will first have an intravenous line placed by experienced Nuclear Medicine staff.

A small amount of Gallium-68 Dotatate, a radioactive imaging agent, is injected into a vein in your arm. You will rest in a recliner for about 50 minutes while the imaging agent circulates through your body. You will then begin an approximate 30 minute imaging session.
The PET/CT scanner is an imaging machine that has 2 donut-shaped rings. One is the PET scanner, which detects and takes a picture of where the imaging agent (Gallium -68 Dotatate) has gone in your body. Second is the CT scanner, which uses x-rays to takes a structural picture of your body. A technologist will position you on the scanner bed. You will be asked to lie still during the scan and while the bed is being moved in and out of the PET/CT scanner.
When the scan is completed, you may be asked to wait until the technologist checks the images. Occasionally, more images may be needed if the first set of images is not clear. The need for additional images does not necessarily mean there was a problem with the exam or that something abnormal was found and should not be a cause of concern for you. The results of the routine Gallium-68 Dotatate scan will be recorded in your medical record.

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

PET/CT scan using Gallium-68 Dotatate

You will have an injection of the PET imaging agent in your arm vein. You may experience mild discomfort and a cold sensation moving up your arm from the injections. The risks from injection include pain, bruising, or rarely infection at the site of the needle stick.

The effect of Gallium-68 Dotatate on a fetus (developing baby still in the womb), or on a breastfeeding infant is unknown and may be harmful. Because of these risks, women cannot take part in this study if they are pregnant or breastfeeding.

Some people with claustrophobia may feel too closed in and may not tolerate the PET/CT scanning. If you feel too confined in the scanner you can inform the technologist and the scan will be stopped.

Most people have no side effects from a Gallium-68 Dotatate PET/CT scan. As with any medication, allergic reactions are a possibility.

Radiation Exposure

You will be exposed to a small amount of radiation from the tracer injection and from the CT (x-rays) during the PET/CT scan. The amount of radiation you will receive has a low risk of harmful effects.

Sedation

Sedation may be offered to relax you during the scan if you are uncomfortable in small spaces. In order to receive sedation, you must have an adult accompany you to your appointment. You may feel drowsy after you receive sedation and you should not drive, operate machinery or sign legal documents within 24 hours of receiving sedation.

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

7. 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 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.

We will tell you about any new information that may affect your willingness to stay in the research study.

8. 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. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments, and coinsurance.

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

This study may not make your health better. However, this study will evaluate a newly developed imaging technique which may be more sensitive to localize the source of the hormone which has caused your low phosphate levels and bone disease. If the tumor is localized, your tumor induced osteomalacia may be surgically treated. Your tumor may not be identified by this newer imaging technique.

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

You don't have to be in this study to receive treatment for your condition.

11. 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 procedure which are done just for this research study. These tests are procedures are:

- PET/CT scan using Gallium-68 Dotatate

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. These tests and procedures are:

- Office Visit
- Any additional visits or tests scheduled, based on the scan results

You will also be responsible for any 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.

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

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

13. What will happen to your samples?

The results of the imaging performed as part of this study will be available in your medical record. No samples will be collected for this study.

14. 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. Data will be entered into a separate database which will not contain any identifiers. All information, research data, and related records will be coded, and this code will be used on all documents to prevent subject identification. The principal investigator will ensure that this document is password-protected, and that both the document and the password are kept in a secure, private hard-drive. This document will be destroyed at the end of the research study. You will not be identified in any publications or presentations that result from this study.

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.
- Wee 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.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- 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.
- The sponsor(s) of this study and the people or groups it hires to help perform this 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, 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.

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Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission 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.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission 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 lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

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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