THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

A Pilot Study of Glutamine PET Imaging of Head and Neck Squamous Cell Carcinoma (HNSCC)

2021-0739

Study Chair: Lesley Flynt

_____ _____
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.

This research has been reviewed and approved by an Institutional Review Board (IRB – a committee that reviews research studies). You may talk to them at (713) 792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

STUDY SUMMARY

The standard imaging methods for head and neck cancers are MRIs and CT scans. PET scans are more sensitive than these standard methods, which means that they may be better able to detect and help manage the disease.

The goal of this clinical research study is to test the abilities of 2 different imaging agents (^{11}C-Glutamine and/or ^{18}F-FSPG) in PET scans to help researchers view the disease.

This is an investigational study. ^{11}C-Glutamine and ^{18}F-FSPG are not FDA approved for this specific use and are considered investigational in this setting. The study doctor can explain how the imaging agents are designed to work.

There are no benefits to you for taking part in this study. Future patients may benefit from what is learned. Researchers hope the information learned in this study may improve imaging methods so that tumors can be found when they are smaller, which may lead to earlier treatment and/or better treatment plans and management.

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. Reasons you may not want to take part in this study include exposure to additional radiation and side effects from the procedures.

You can read a full list of potential side effects below in the Possible Risks section of this consent.

Your active participation in this study is expected to be made up of 2 separate PET scans. These can be performed on the same day, but can also be done on separate days. If receiving both scans on the same day, the total time you will be scanned will be about 1¼ hours, and the total time you will need to be in the PET facility will be about 5 ½ -6hours. If receiving the scans on separate days, the total time you will be scanned will be about 1 hour, and the total time you will need to be in the PET facility will be about 2 ½ - 3hours each day.

Rarely, the availability of the imaging agents may be limited. If this happens, you will have only 1 PET scan with either ^{11}C-Glutamine or ^{18}F-FSPG.

Your study doctor may stop your taking part in this research if the disease gets worse, if intolerable side effects occur, if the study is stopped, if you are unable to follow the study directions, or if the study doctor thinks it is no longer in your best interest. If you are taken out of this study, you will be told the reason why.

The research PET scan(s) will be performed at no cost to you.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard-of-care imaging. You can choose to receive standard-of-care treatments or other investigational agents as recommended by your doctor. Declining to take part in this imaging study will not affect your care at this institution nor affect your eligibility to take part in other clinical studies at MD Anderson. If you decide not to take part in this study, it will not affect your treatment options. Your doctor will discuss your options with you.

1. STUDY DETAILS

Up to 20 participants will be enrolled in this study. All will take part at MD Anderson.

If you agree to be in this study, you will have 2 research PET scans: an ^{11}C-Glutamine PET scan and an ^{18}F-FSPG PET scan. It is preferable for both the ^{11}C-Glutamine PET scan and ^{18}F-FSPG PET scan to happen on the same day, but if this is not possible they can be done on separate days. If both scans take place on the same day, the ^{11}C-Glutamine PET scan should take place first. There will be about 3½ hours between your injection of ^{11}C-Glutamine and ^{18}F-FSPG.

If the PET scans happen on separate days, the order of the scans is not important, but both scans must be within 7 days of each other.

If only 1 PET scan can be performed because the availability of the imaging agents is limited, the study doctor will tell you if you will have the ^{11}C-Glutamine PET scan or the ^{18}F-FSPG PET scan.

Before the first scan:

- You must fast (not eat or drink anything except for water) for at least 6 hours (but preferably 12 hours).
- You should limit your food to a low-carbohydrate diet the day before the scan. Strenuous exercise (such as weight lifting, running/jogging, cycling, and so on) should also be avoided for 24 hours before the PET scan.
- You should keep well-hydrated with water, and any medications should only be taken with water.
- You must not smoke, perform any smoking-related activities (for example, vaping), or use tobacco products after midnight the night before your PET scan.

On the day of the scan(s):

- A small tube (called an IV) will be placed in a vein in your arm through which you will receive the radioactive material for the PET scan(s). Although using an IV is preferred, if you have a port in place, your port may be used for this administration (if the doctor agrees).
- You will be asked about the last time you ate and blood (about ½ teaspoon) will be drawn to check your blood sugar level.
- The results of your standard CT scans or MRIs will be collected before the PET imaging to check the status of the disease.
- If you can become pregnant, blood (about 2-3 teaspoons) will be drawn or urine will be collected for a pregnancy test. To take part in this study, you must not be pregnant.

You will be asked to lie on your back on the PET scanning table with your arms resting above your head and ^{11}C-Glutamine will then be given through the IV or your port. You will lie in the PET scan for up to about 1 hour. Several types of images will be done during this time.

You will be asked to empty your bladder right after the first scan. You will be asked to drink 2 large cups of water between the scans (if you have both on the same day), and will be asked to empty your bladder again before the second scan.

After you drink water and empty your bladder, you will receive an injection of ^{18}F-FSPG through your IV or your port. You will be asked to recline/rest comfortably in a still position within a dimmed room for about 1 hour after the injection. Then, for the second scan, you will be asked to lie on your back on the PET scanning table with your arms resting above your head so PET scans can be done. The total scanning time is about 20 minutes.

You will be asked to empty your bladder again before you leave the imaging clinic, and every 2 hours for the next 6 hours after that.

Follow-Up
You will be called between 1-14 days after the imaging scans and asked about how you are doing. Each call should take about 5-10 minutes.

In addition, you will be monitored for side effects during and up to 30 days after the research PET imaging scans. This may be done by reviewing your medical record, a standard clinic visit, or a phone call. If you are called, this should take about 5-10 minutes.

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.

A **PET scan** may cause you to feel “closed in” while lying in the scanner. However, the scanner is open at both ends and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or technicians will give comfort or the scanning will be stopped.

The PET scan exposes your body to radiation. The radioactive solution does not remain 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.

During the PET scans, you will also have brief CT imaging performed. **CT scans** send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped.

Just like with any medication, you could have an allergic reaction to the medications you are receiving in this study. Minor reactions, including headache and nausea, may occur

due to administration of the radioactively labeled drugs. Although there are no known side effects to either **^{11}C-Glutamine or ^{18}F-FSPG** when given in an IV or through your port, there is a rare chance of an allergic reaction or other side effect to radioactively labeled drugs. This can range from a mild skin rash to a more severe reaction, such as throat tightness, difficulty breathing, lowered blood pressure and rarely, death.

Fasting may cause you to feel tired, hungry, and/or nauseous. If you have diabetes, fasting may cause your blood sugar to drop. It is important to talk to your doctor about managing your blood sugar while fasting.

Having an **IV** placed may cause slight discomfort when the needle is inserted into the vein. It may cause momentary discomfort during the puncture, light-headedness, fainting, soreness and/or bruising for several days. In very rare circumstances, either bleeding or infection can develop at the needle puncture site.

If your existing **port** is used to deliver the contrast agent, you may be at risk for infection.

Using the imaging agents together may cause side effects that are not seen when each is given alone. The study drug combination may also increase the frequency and/or severity of the side effects listed above.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks

Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant or breastfeed a baby while on this study.

If you can become pregnant, you and your sexual partner(s) must use adequate birth control (birth control pills, implants, or barrier methods like condoms or diaphragms) during the study and until your last research PET scan is completed, if you are sexually active.

Talk to the study doctor about which birth control methods are acceptable to use during the study.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant will result in your removal from this 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 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.

In compensation for your time and effort in this study, you will be paid a total of $200 dollars per PET agent you receive. This means you may receive $200-$400, depending on how many scans you complete. You will receive a separate information sheet with more information about this compensation. To receive this compensation, you must complete, sign, and date this sheet and return it to the study staff.

Additional Information

4. You may ask the study chair (Dr. Lesley Flynt, at 713-745-8760) 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, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson. Reasons why you may be removed from the study include, but are not limited to, not following directions, having intolerable side effects, or because the study doctor thinks your participation in this study may be harmful to you.

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.

   If you want to receive the results of the investigational PET scans, please ask the study doctor. However, the results of these research (investigational) scans will not be used to make changes to your treatment plan.

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

Future Research

Data

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

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

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.

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
   - 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

   Data collected about you will be labeled with a code and will not contain information that will identify you, such as your name, age, or birth date. All PET/CT imaging data will be kept per MD Anderson policy on password protected computers behind the institution firewall for future review and the research project. This data will be stored indefinitely (without a time limit) and only study staff working on this project will have access to it.

   Results of the testing will be shared only with the study doctors. Any published data will not contain information that could identify you.

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 **2021-0739**.

_____ _____
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 (OTHER THAN TRANSLATOR, PARENT/GUARDIAN, OR STUDY CHAIR)	DATE

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION