Cancer Consent

Project Title: CASE 13219; Comparison of yttrium-90 absorbed doses using PET/CT versus PET/MR imaging in patients undergoing selective internal radiation therapy for hepatic malignancies.

Sponsor: Siemens Medical Solutions

Principal Investigator(s): Ram Gurajala, M.D., Phone Number: 216-444-5163

Cancer research studies are coordinated by physicians and scientists from Cleveland Clinic, University Hospitals and Case Western Reserve University (CWRU) through the NIH National Cancer Institute (NCI) designated Case Comprehensive Cancer Center (Case CCC). The goal of this collaboration is to enhance cancer treatment and research in Northeast Ohio. This study is being offered at Cleveland Clinic (CC).

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are scheduled for Y-90 radiation bead embolization of your liver tumor to be followed by an immediate PET/CT to assess the distribution, which is standard care of practice at the Cleveland Clinic.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to compare the results of positron emission tomography/computer tomography (PET/CT) to positron emission tomography/magnetic resonance imaging (PET/MRI) to help determine any added advantage of one over the other in relation to a tumor which might assist in further management plans.

How long will the research last and what will I need to do?

You will be asked to have a one-time PET/MRI procedure in addition to the clinically ordered PET/CT. The PET/MRI procedure will take place after your Y90 radioembolization procedure either before or after the PET/CT. You will not be getting any IV contrast dye for either the PET/CT or the PET/MR.

Your participation in the research will last about 30 - 45 minutes.

More detailed information about the study procedures can be found under "What extra tests and procedures will I have if I take part in this study?"

Is there any way being in this study could be bad for me?

There are no known biological risks associated with PET/MR imaging. A PET/MRI may cause possible anxiety for people due to the confined space of the testing area (resulting in feelings of claustrophobia) and the loud banging made by the machine.

More detailed information about the risks of this study can be found under "What possible risks can I expect from taking part in this study?"

What possible benefits can I expect from taking part in this study?

There is no personal benefit to you by participating in this research study. The knowledge to be gained from this research may be beneficial for other patients, society or science.

What are my other choices if I do not take part in this study?

The alternative to being in this study is to not take part.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

You are being asked to take part in a research study because you are scheduled for Y-90 radiation bead embolization of your liver tumor to be followed by an immediate PET/CT to assess the distribution, which is standard care of practice at the Cleveland Clinic. A PET/CT is a specialized CT which also includes PET which detects the distribution of radioactivity in the body. This allows your physicians to assess the distribution of the radioactive beads within your body, particularly within your liver and the tumor. These results assist your physician in planning the next step in your care - either additional treatment or imaging follow up. PET/MRI is a newer scanning technique which also gives information regarding the distribution of the beads, but has better imaging of soft tissues and solid organs, such as your liver. The PET/MRI may be able to provide additional information regarding the distribution of the beads as well as the liver lesions including the characteristics of the lesions due to its higher soft tissue definition. This study is being conducted to compare the results of the PET/CT to the PET/MRI to help determine any added advantage of one over the other in relation to the tumor which might assist in further management plans.

What extra tests and procedures will I have if I take part in this study?

This study involves a one-time PET/MRI procedure in addition to the clinically ordered PET/CT. The PET/MRI procedure will take place after your Y90 radioembolization procedure either before or after the PET/CT. You will not be getting any IV contrast dye for either the PET/CT or the PET/MR.

PET/MRI is a hybrid imaging technology that incorporates magnetic resonance imaging (MRI), which gives excellent soft tissue structural imaging, and positron emission tomography (PET) which gives details on how tissues and organs operate and provides information on the radiation dose and distribution. The PET/MRI does not involve radiation like the PET/CT. It is slightly more time consuming than PET/CT however it should not take more than 45 minutes.

The MRI scans the soft tissue characteristics of the body. A PET/MRI includes the measurement of the metabolism to determine how things work.

Once you have completed the research procedure (the PET/MR), your involvement in the study is complete. We would also like to access your medical records to collect basic medical information like your demographics, age, diagnosis, treatment details, and information regarding the results of your PET/CT and PET/MR.

What possible risks can I expect from taking part in this study?

Magnetic Resonance Imaging (MRI)
If you take part in this research, you will have an MRI (magnetic resonance imaging). MRI uses a magnet and radio waves to make images (pictures) of the inside of the head and/or body. There have been no ill effects reported from exposure to the magnetism or radio waves used for these studies; however, it is possible that harmful effects could be recognized in the future. A known risk is that the magnet could attract certain kinds of metal that may cause injury to you. We will ask you about metal within your body (this includes certain dyes used in tattoos and body piercings). If there is any question about potentially hazardous metal within your body, you will not be able to participate in this research study. An MRI might cause possible anxiety for people due to the confined space of the testing area, resulting in feelings of claustrophobia. In addition, the MRI scanner makes a loud buzzing noise that could affect hearing ability. You will be provided with earplugs or headphones and assistance in their use in order to protect your hearing. You will be able to communicate with the scanner technologist using an intercom and/or signaling device. The technologist will try to help you feel as comfortable as possible in the scanner. You can ask to stop the scan and be removed from the scanner at any time by using the intercom or signaling device.

Confidentiality Risks
There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential. If you decide to be in this study, the study researchers will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be kept for the length of the study. After that time it will be destroyed or de-identified,

meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the principal investigator or selected members of the research team. Any information that can identify you will remain confidential. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.

What happens to the information collected for the research?

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Can I stop taking part in this study?

Yes. You can decide to stop at any time.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

What are the costs of taking part in this study?

Your involvement in this research study is voluntary and you will not be paid for your participation.

Some of the services you will receive during the time you are participating in this research study are considered to be conventional routine clinical services that you would have received even if you were not participating in the research study and will be billed to you or your health insurance plan. This includes the PET/CT after the embolization procedure. You will not be charged for the PET/MR done for this study, or for the medical data collection.

What happens if I am injured or hurt because I took part in this study?

If you believe that you are injured as a result of the research procedures being performed, please immediately contact the study doctor.

If injury occurs as a result of your involvement in this research, medical treatment is available from Cleveland Clinic, but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Further information about research-related injuries is available by contacting the Cleveland Clinic Institutional Review Board at (216) 444-2924.

HIPAA AUTHORIZATION
Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you volunteer to participate in this research, your protected health information (PHI) that identifies you will be used or disclosed to Ram Gurajala, MD, and the research study staff at Cleveland Clinic for the purposes of this research and to Case Western Reserve University for administration.

The PHI that we may use or disclose (release) for this research may include your name, address, phone number, date of birth, Social Security number, information from your medical record, lab tests, or certain information relating to your health or condition..

Some of the tests and procedures done solely for this research study may also be placed in your medical record so other doctors know you are in this study. Upon completion of the study, you may have access to the research information that is contained in your medical record.

In addition to the investigators and research staff listed above, your PHI may be looked at by other groups involved with the study such as the Cleveland Clinic Institutional Review Board, and the Case Comprehensive Cancer Center Protocol Review and Monitoring Committee. Your PHI may also be used by and/or disclosed (released) to:

- Siemens Medical Solutions, its study monitors and representatives;
- Siemens Medical Solutions, collaborators and licensees;
- Case Comprehensive Cancer Center members and collaborators;
- The Food and Drug Administration;
- The Department of Health and Human Services;
- The National Cancer Institute (NCI);
- Data Safety and Monitoring Boards;

Once your personal health information is released it may be re-disclosed and no longer protected by privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to:

Ram Gurajala, MD
Case Comprehensive Cancer Center
Cleveland Clinic
9500 Euclid Ave.
Cleveland, OH 44195

Your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of this research. Also, information already disclosed outside the Cleveland Clinic cannot be retrieved. This will not affect your rights to treatment or benefits outside the research study.

The Cleveland Clinic will not use your information collected in this study for another research purpose without your written permission; unless the Cleveland Clinic Institutional Review Board (IRB) assures your privacy and confidentiality is protected. The IRB is a committee whose job it is to protect the safety and welfare of research subjects.

By signing this informed consent form, you are authorizing such access to your research and medical record information. If you choose not to sign this consent form, you will not be able to participate in this research study. This Authorization does not have an expiration date.

Voluntary Participation
Your participation in this research study is voluntary. Choosing not to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed.

In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating.

Questions about the Research
If you have any questions, you can ask the Principal Investigator and/or research staff at:
216-444-5163.

Emergency or after-hours contact information
If you are a Cleveland Clinic patient, you should contact the page operator at (216) 444-2200 or toll free at (800) 223-2273, and ask for the oncologist (cancer doctor) that is on call.

Where Can I Get More Information?

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about: concerns regarding the study, research participant's rights; research-related injury; or other human subjects issues, you may contact the Institutional Review Board (IRB) at Cleveland Clinic IRB 216-444-2924.

You may call the National Cancer Institute's Cancer Information Service at:
1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

You will get a copy of this form. If you want more information about this study, ask your study doctor.

US National Institutes of Health (NIH) Clinical Trial Database:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, if applicable, 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.

Signature
Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

_____	_____	_____
Signature of Participant	Date	Printed Name of Participant

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____	_____
Signature of Person Obtaining Consent	Date

_____
Printed Name of Person Obtaining Consent