THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Advanced MRI for Intracranial Metastasis Treated with Stereotactic Radiosurgery

2019-1008

Study Chair: Jason Johnson, MD

_____ _____
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).

STUDY SUMMARY

The goal of this clinical research trial is to study different types of investigational imaging techniques (called "sequences") during MRIs of the head before and after radiation therapy in patients with intracranial metastases (cancer that has spread to the brain). The researchers will also compare these new techniques with standard MRI imaging to see if the investigational techniques provide better images.

One of these sequences (acidoCEST) involves imaging before and after injection of a contrast (iopamidol), which is an FDA approved agent for CT imaging. Its use for this purpose is considered investigational. Patients with a history of kidney problems or prior reaction to imaging contrast agents will NOT be offered this portion of the study.

This is an investigational study. Most of the MRI sequences are delivered using FDA approved and commercially available methods. Some of the imaging sequences used in this study are not FDA approved or commercially available. It is considered investigational to use these imaging techniques as well as acidoCEST imaging with iopamidol during the MRI.

The MRI you receive on this study could provide better quality images than you would normally receive from a standard MRI scan. Future patients may benefit from what is learned. There may be no benefits for you in this study.

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 time commitment. Your MRI will take longer to complete than the standard-of-care MRI.

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

Your participation in this study will be over after your last research MRI is completed.

The research MRI and acidoCEST imaging with iopamidol will be provided at no cost to you while you are on study. You and/or your insurance provided will be responsible for the cost of the standard-of-care MRI and contrast drug.

You may choose not to take part in this study. The study doctor will discuss the possible risks and benefits of this option. Instead of taking part in this study, you may choose to receive a standard MRI without the investigational sequences used in this study. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

Up to 50 patients will be enrolled in this study. All will take part at MD Anderson.

Imaging Visits

If you agree to take part in this study, you will visit the Diagnostic Imaging Clinic 8 times to have MRIs performed. The first visit will occur within 14 days before your scheduled radiation therapy (a baseline visit). The other 7 visits will occur every 4-16 weeks after the start of your radiation therapy.

At each visit, you will have two (2) types of MRI sequences: standard-of-care MRI sequences (nearly identical to what you would receive if you did not take part in this study) and the study's investigational research sequences (which may include acidoCEST). Your routine MRI of the brain can be scheduled and performed along with the research MRI scan. The research sequences will add about 30 minutes to your appointment.

The total time for each imaging visit should be about 1 hour.

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.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI imaging agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the imaging agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

Iopamidol is FDA approved as a contrast agent for CT imaging and is considered safe for most people. Iopamidol may cause a feeling of warmth or pain at the injection site. It may cause nausea, vomiting, headache, dizziness, and/or heart and kidney complications. It may cause allergic reactions, which may include breathing and/or skin problems (rash, redness, blisters, itching, and/or local swellings) and may appear either right away or up to a few days after the injection. It may cause water to collect in the lungs and/or anaphylactic shock (a severe allergic reaction that can cause breathing difficulty and/or a drop in blood pressure). It may cause changes in the way you move or changes in your senses. If you have had a prior reaction iopamidol or another CT contrast agent, please tell the research staff as this portion of the study may not be safe for you.

This study may involve unpredictable risks to the participants.

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 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.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets during the study and will continue to be stored securely after the study. Only authorized study members will have access to study data.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Jason Johnson, at 713-792-8443) 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.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can continue to collect data from your routine medical care. If you agree, this data will be handled the same as research data.

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.

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.

You will receive the results of your research MRI, but the test results will not be included in your medical record or used in your treatment planning.

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

Future Research

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

Before being 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 this 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 you do not want your data to be used for future research, tell the study doctor. You may withdraw your participation at any time by telling your study team. If you decide to withdraw, the data and test results already collected from your scheduled procedures will be kept and may be used.

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

- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

The data collected about you will be labeled with a code and will not contain information that will identify you, such as your name or age. All MR 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 5 years after the end of the study and only study staff working on this project will have access to it.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

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 **2019-1008.**

_____ _____
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