THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Feasibility of Navigated Transcranial Magnetic Stimulation (nTMS) of Patients treated with Stereotactic Radiosurgery for Brain Metastases in the Motor Cortex: A Comprehensive Cross-sectional Assessment 2019-0302

Study Chair: Caroline Chung

_____ _____
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

Brain metastases are the most common brain tumors in adults and treatment includes radiation and surgery. Stereotactic radiosurgery (SRS), a type of radiation therapy, delivers high dose radiation. While this dose is effective, there is a small chance of causing injury to the brain and surrounding areas, which can then lead to side effects. Because of this, a number of areas of the brain have limits on the dose of radiation that can be used. However, there are currently no dose limits for the motor cortex (part of the nervous system that controls muscle movement), because current imaging techniques are not advanced enough to define an individual patient's motor nerves.

Navigated Transcranial Magnetic Stimulation (nTMS) is a non-invasive tool that uses sensors on a patient's muscle to trace the location in their brain that controls that muscle, as viewed on an MRI machine. This tool is currently used by neurosurgeons to decide where to operate so as to not damage the motor nerves. However, it is not currently being used to plan for SRS.

You are being asked to take part in this study because you have already had SRS to treat a brain metastasis (cancer that spread) near your motor cortex and an MRI was used to plan it.

The goal of this clinical research study is to learn if nTMS can be used to plan for SRS and to help decide on a maximum radiation dose that can be used on motor nerves. Researchers want to use a series of simple physical tests and questionnaires to learn if nTMS can more effectively help plan radiation treatment using SRS than MRI.

This is an investigational study. nTMS will be performed using FDA-approved and commercially available methods. It is investigational to use nTMS to plan SRS.

Future patients may benefit from what is learned on this study. There are no benefits for you in this study because you already had your SRS treatment. You will just have a series of tests checking your motor function, which may help researchers find any problems you have and assist in referral to therapy, if required.

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. If you take part in this study, you may experience the inconvenience of an additional two-hour session on the day of your regularly scheduled follow up visit.

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

Your participation in this study will consist of one study visit, in which you are at the clinic 2 hours longer than you would be normally.

There will be no cost to you to participate in this study.

You may choose not to take part in this study.

1. STUDY DETAILS

Up to 22 participants will be enrolled in this study. All will take place at MD Anderson.

If you agree to take part in this study, at the time of your next regularly scheduled follow up visit with your radiation oncologist, you will also be scheduled for a 2-hour nTMS session.

During the first hour of this session, you will have nTMS performed on your brain. For this procedure, sticker muscle sensors will be placed on your body and you will be asked to activate different muscle groups (for example, flex your arm). At the same

time, an nTMS provider will use a magnet on your head to see how your nerves work to do this.

During the second hour, you will perform 4 different tasks that test grip strength, pinch strength, and ability to use and feel with your hands. You will also complete 3 one to two page questionnaires about your motor function and quality of life after you have had SRS. These questionnaires will take about 15 minutes to complete, in total.

You may be taken off study if the doctor thinks it is in your best interest.

2. POSSIBLE RISKS

While on this study, you are at risk foAr 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.

nTMS uses magnets, so there is no risk of radiation exposure. Possible side effects include fainting and headache. Another possible side effect is seizures. Sometimes nTMS is used at a much higher strength than will be used in this study for treatment of other conditions. No seizures have ever been reported with the use of nTMS for mapping regions of the brain.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

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 and will continue to be stored securely after the study.

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 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.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive a gift card to reimburse you for the cost of parking for your regularly scheduled follow up visit and the additional two-hour session required for this study for a total value of $30. This will be provided at the second study visit.

Additional Information

4. You may ask the study chair (Dr. Caroline Chung, at 713-563-2300) 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. The study staff may ask if they can continue collecting the results of routine care from your medical record.

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, and you may be asked to sign another informed consent and authorization form stating your continued willingness

to participate in this study.

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 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

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use 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 **2019-0302**.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the

short form consent process (VTPS) and patients who are illiterate._____
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 DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION