



Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Clinical impact of a biomechanical deformable registration volumetric image method for percutaneous Ablation on patients with malignant Liver Lesions (COVER-ALL)
2019-0213

Study Chair: Bruno C. Odisio

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 current standard for targeting tumor cells and evaluating the outcome of a liver ablation procedure (in which tumor cells are destroyed using microwaves or radiofrequency ablation) is a visual inspection of the pre- and post-procedure CT scans.

The goal of this clinical research study is to learn if a software-aided imaging system called Morfeus can help to improve the accuracy and effectiveness of liver ablation.

This is an investigational study. The microwave ablation on this study is performed using FDA-approved and commercially available methods. Morfeus is an FDA-approved method for radiation therapy. It is investigational to use the software during a liver ablation.

Future patients may benefit from what is learned on this study. The Morfeus software may help the ablation procedure be more accurate and/or effective. 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 side effects, potential expenses, and time commitment.

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

The ablation procedure will be performed in 1 day. Your participation in this study should last about 3 years and will be over after the last follow-up visit.

You and/or your insurance provider will be responsible for the costs of the ablation procedure. The Morfeus software will be used at no cost to you.

You may choose not to take part in this study. You may have liver ablation without taking part in this study. The study doctor will discuss with you the possible risks and benefits of this alternative treatment.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will help the doctor decide if you are eligible:

- Your medical history and results of previous MRIs and biopsies will be collected to learn more about the type of liver cancer you have.
- You will complete 2 questionnaires about your quality of life, which will take about 5 minutes. You will also be asked about how much pain you may be experiencing.
- You will have an ultrasound or CT scan of the liver to check the status of the disease.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other treatment options will be discussed with you.

Up to 120 participants will be enrolled in this study. All will take part at MD Anderson.

Study Procedures

If you are found to be eligible to take part in this study and you are 1 of the first 50 participants enrolled, you will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups: control or experimental. Your doctor will know which group you are in at the time of the ablation procedure. You will know which group you were enrolled in at the end of the procedure. If you are enrolled after 50 participants, you will be assigned to the experimental group.

All participants will have the ablation procedure done as routinely performed. You will sign a separate consent form for the ablation procedure that describes it in more detail, as well as its risks. The difference between the 2 groups is that the participants enrolled on the experimental group will have their ablation images processed by the Morfeus software. Based on the software's information, your doctor may want to perform further ablation on the tumor during the same procedure.

On the day of your ablation procedure, you will have a CT scan to check the status of the disease.

You will then be given anesthesia to put you to sleep for the ablation procedure. After this happens, the ablation probe will be placed using an ultrasound or CT scan. Then, additional CT scans and/or ultrasounds may be performed to check if the ablation probe has been placed in the best position.

After this, participants in the control arm will have the ablation procedure. For participants in the experimental arm, the study doctor will use the Morfeus software to further check the placement of the probe. The probe may then be moved based on the results of the software check. Then you will have the ablation procedure.

After the ablation procedure, additional ultrasounds and/or CT scans will be performed to check how successful the study doctor was at targeting the lesion tissue and not the surrounding tissue. Again, for patients on the experimental arm, these CT scan images will be processed by the software to check that the procedure has been thoroughly done.

Follow-Up

Within 1-2 months and then about 3, 6, 12, 24, and 36 months after the ablation procedure:

- Blood (about 1 tablespoon) will be drawn for routine tests.
- You will have a CT scan to check the status of the disease.
- At the first 4 follow-up visits, you will complete the quality of life questionnaires.
- At the first follow-up visit only, you will be asked about any pain you may be experiencing.

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.

You will sign a separate consent form that describes the risks of the liver ablation procedure. The only additional risks that you may experience by taking part in this study are due to an increased amount of CT scans and blood draws.

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. When a CT scan of the abdominal area is taken, material may be inserted into the rectum to better define the bowel. You will usually drink liquid to help define various abdominal organs. This may cause nausea and/or vomiting. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

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 research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this CoC cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below).

The CoC cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation. You should understand that a CoC does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The CoC will not be used to prevent disclosure for any purpose you have consented to.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks

Taking part in this study can result in risks to an unborn baby, so you should not be pregnant while receiving ablation.

If you are pregnant, you will not be enrolled on 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 or the National Institutes of Health 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 no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Bruno C. Odisio, at 713-563-1066) 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 National Institutes of Health (NIH) Research Project Grant (R01) program, 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.
9. This study is sponsored and/or supported by: the National Institutes of Health (NIH) Research Project Grant (R01) program.

Future Research

Your personal information and/or samples are being collected as part of this study. These data and/or samples 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 and/or samples. 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 or samples 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 and/or samples 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 and/or samples.

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.

Genetic Research

Samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

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
 - The National Institutes of Health (NIH) Research Project Grant (R01) program, who is a sponsor or supporter of this study, and/or 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

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. If you withdraw from the study, the study staff may ask if they can continue collecting the results of routine care from your medical record.
- 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 2019-0213.

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