

NCT05609331

2022-0371

IRB APPROVED

AS MODIFIED

Jul 10, 2023

Informed Consent/Authorization for Participation in Research

TITLE: Feasibility, Safety, and Efficacy of Stereotactic MRI-Guided Adaptive Radiation Therapy (SMART) for Central Lung Tumors

PROTOCOL NO.: 2022-0371
WCG IRB Protocol #20224824

SPONSOR: MD Anderson Radiation Oncology Strategic Initiative

INVESTIGATOR: Saumil Gandhi, MD
1515 Holcombe Blvd. Unit Number 97 Room B2. 4840
Houston, Texas 77030
United States

**STUDY-RELATED
PHONE NUMBER(S):** 713-563-2300
713-563-8490
713-792-2121 (24 hours)

 Participant's Name

 Medical Record Number

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

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?

You are invited to take part in a research study because you have lung cancer.

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 goal of this clinical research study is to learn if using MRI (magnetic resonance imaging) to guide radiation therapy can help to control central lung cancer. The results of the MRI-guided radiation therapy will be compared to conventional radiation therapy (guided by CT scans) during this study. The safety of MRI-guided radiation therapy will also be studied.

This is an investigational study. Radiation therapy is delivered using FDA approved and commercially available methods. It is considered investigational to use MRI-guided radiation therapy to help control central lung cancer. The study doctor can explain how the study therapy is designed to work.

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

You may be able to receive radiation for up to 3 weeks, depending on what the study doctor thinks is in your best interest. You will be in follow-up for up to 1 year after radiation therapy.

During this study, you will be asked to receive radiation therapy and have regular imaging scans.

More detailed information about the study procedures can be found under ***“What happens if I agree to be in this research?”***

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

If you take part in this study, you may experience side effects related to the MRI, which may include claustrophobia or complications with implanted devices.

More detailed information about the risks of this study can be found under ***“Is there any way being in this study could be bad for me? (Detailed Risks)”***

Will being in this study help me in any way?

It cannot be promised that there will be any benefits to you or others from your taking part in this research. However, the radiation therapy may help to control the disease. Future patients may benefit from what is learned.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Instead of being in this research study, your choices may include receiving standard radiation therapy or other approved therapies outside of this study. You may choose to receive other investigational therapy, if available. These alternative treatments have risks and benefits that may be the same or different than those in this research study. The study doctor can discuss these alternative treatments, including their risks and benefits with you.

If you decide that you don't want any more active treatment, one of your options is called “comfort care.” Comfort care includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually this care can be provided at home.

If you think you might prefer comfort care, please discuss this with your family, friends and your doctor.

In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

Detailed Information

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

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 713-563-2300, 713-563-8490 or 713-792-2121 (24 hours).

This research has been reviewed and approved by an Institutional Review Board (IRB – an ethics committee that reviews research studies). If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

WCG IRB
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 855-818-2289
E-mail: researchquestions@wcgirb.com

WCG IRB is a group of people who perform independent review of research.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

How many people will be in this study?

It is expected about 20 people will be enrolled in this research study. All will take part at MD Anderson.

What happens if I agree to be in this research?

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:

- You will have a physical exam.
- You will have a CT scan and/or MRI to help the study doctor plan your radiation therapy. If you are unable to have an MRI for any reason (such as if you have a metal implant or a defibrillator), you will not be able to take part in this study.
- If you can become pregnant, blood (about 2 teaspoons) or urine will be collected for a pregnancy test. To take part in this study, you must not be pregnant.

If you have had some of the above tests and procedures performed recently, they may not need to be repeated during screening.

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.

Study Groups

If you are found eligible to take part in this study, you will be assigned to 1 of 2 study groups based on when you join the study:

- If you are in **Group 1**, you will receive treatment with the conventional CT-based radiation therapy and receive additional MRI scans.
- If you are in **Group 2**, you will receive treatment with the investigational MRI-guided radiation therapy.

Ten (10) participants will be assigned to each group. The study doctor will tell you which group you are assigned to.

Study Therapy

Before you begin receiving radiation, you will have a **radiation simulation**. This involves going through the steps of receiving radiation to help you understand the radiation process, though you will not receive any radiation during the simulation. This will also help the doctor know where to “aim” the radiation when you receive it. This simulation may take about 1 hour.

You will be assigned to a **radiation schedule** based on the results of the simulation. The study doctor will tell you how often you will receive radiation therapy. You may receive it for 1-3 weeks. This therapy will be guided by CT or MRI imaging based on which study group you are in.

During your radiation therapy, you will also have regular **MRIs**. If you are in Group 1, these MRIs will be performed on 2 days during your therapy to help plan the MRI-guided therapy given to patients in Group 2. If you are in Group 2, these MRIs will be performed every day as part of your therapy.

Follow-Up

Every 3 months during Year 1 and whenever the study doctor thinks it is needed during Year 2, you will have follow-up visits. During these visits, you will be asked about any side effects you have had, and your medical history will be recorded. You will also have a CT or PET/CT scan of your chest to check the status of the disease.

If you are unable to come to MD Anderson for your follow-up visit, the study team will call you to collect the above information. This call should take about 10 minutes.

After 1 year of follow-up, you will continue to have follow-up as part of your standard of care (collecting information about any side effects that you may have and your medical history). If the follow-up is at another hospital, the information about your medical history, physical exams, lab tests, and PET, MRI, or CT scans will be sent to MD Anderson for review.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for the following:

- Tell the study doctor/study staff about all medications that you are taking or plan to take, including prescription and over-the-counter medications, supplements, vitamins, and herbal remedies.
- Tell the study doctor if you have any metal or medical implants, which may interfere with the MRIs you receive in this study.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

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 who can then decide if you need to have any visits or tests to check on your health. 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 collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Side effects will vary from person to person, and some may occur after you have stopped receiving treatment. Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs/procedures.

Radiation Therapy Side Effects

It is not known how often the side effects of radiation therapy may occur.

<ul style="list-style-type: none"> • swelling • swelling of the arms or torso • skin changes (possible dryness, itching, peeling, and/or blistering) • headache 	<ul style="list-style-type: none"> • hair loss at the treatment site • mouth problems • trouble swallowing • nausea • vomiting • diarrhea • brain tissue damage (necrosis) 	<ul style="list-style-type: none"> • urinary and/or bladder changes • sexual changes • inability to produce children • joint problems • secondary cancers
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Radiation therapy may cause you to develop another type of cancer. Side effects may not occur for up to 6 months after radiation therapy is over. Side effects will vary depending on what part of the body is receiving radiation therapy.

Other Risks

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.

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 contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast 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.

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. 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.

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.

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.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Pregnancy Related Risks

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

Birth Control Requirements: You must use birth control during this study if you are sexually active. Talk with the study doctor about acceptable methods of birth control to use while on study and for how long you should use them.

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.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Will it cost anything to be in this study? Will I be paid to be in this study?

You and/or your insurance will be responsible for the cost of the radiation therapy, imaging, and any other tests performed as part of your standard medical care.

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.

You will not receive any compensation for taking part in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

A participant study number will be assigned to you once you have been enrolled in the study. This participant study number will be used to identify your data in the study report and when reporting any data from the study.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By

signing this document, you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data or samples be used for 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.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Can I be removed from the research study without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

What happens if I get hurt from being in this study?

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or sick and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)

- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form or show them your participant card)
- If you suffer a study-related injury, you may contact the Chair of the study, Dr. Saumil Gandhi at 713-563-2300, or 713-792-2121 (24-hours) with any questions you may have. By signing this consent form, you are not giving up any of your legal rights.

There are no plans for you to be reimbursed for expenses or compensated financially by MD Anderson for this injury. Costs of treatment received because you were hurt or sick will be billed to you or your insurance company. No other form of payment is planned.

You may also call WCG IRB at 855-818-2289 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

What else do I need to know?

This research is being funded by the MD Anderson Radiation Oncology Strategic Initiative.

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

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

Part of your care may be provided outside of MD Anderson by your home doctor(s).

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)
 - WCG IRB
 - 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 and may be re-disclosed.

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**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