THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

MRI-Guided Stereotactic Body Radiotherapy for the Treatment of Early Stage Kidney Cancer: A Single Arm Phase II Clinical Trial (MRI-MARK)

2020-0168

Subtitle: MRI-guided kidney SBRT

Study Chair: Chad Tang, 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.

STUDY SUMMARY

The goal of this clinical research study is to learn if targeted high-dose radiation therapy that uses a new MRI-guided radiation therapy technique can help to control early-stage kidney cancer. The safety of the radiation therapy will also be studied.

This is an investigational study. MRI-guided radiation therapy is FDA approved and commercially available for the treatment of many types of cancer. It is considered investigational to treat early-stage kidney cancer with radiation therapy.

The study doctor can explain how the radiation therapy is designed to work.

The radiation therapy may help to control the disease. Taking part in this study may also provide a non-surgical and non-invasive option for the treatment of the disease. 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 side effects, potential expenses, and time commitment. You may not want to take part in this study because of the prolonged duration or potential claustrophobia of the MRI scans. If you live outside of the Houston area, taking part in this study may require a prolonged stay out of town.

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

You will have 3 doses of radiation therapy. You will then have clinic visits for up to 2 years after your last dose of radiation therapy.

You and/or your insurance provider will be responsible for the cost of radiation therapy and MRI follow-up scans. The additional study biopsies will be done at no cost to you.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive a tumor ablation procedure with interventional radiology, have surgery to remove the tumor, or undergo surveillance (no treatment with frequent imaging). 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

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 be performed to help the doctor decide if you are eligible:

- You will have a physical exam.
- You will complete a questionnaire that contains questions about your demographics (education, income, marital status, and so on) and how your financial well-being has been affected by the disease or its treatment. This questionnaire should take about 10-15 minutes. The financial questionnaire will not be used to determine if you are eligible for the study, but will be compared to your responses later in the study.
- You will have a tumor biopsy to check the status of the disease. Leftover tumor tissue from a previous procedure, if available, may be used instead of this fresh biopsy.
- You will have an MRI and a CT scan to check the status of the disease.
- You will have a split function renal test to check your kidney function. This test involves injection of a small amount of radioactive chemical in your vein which moves through the kidney and can be seen with a special camera. It should take about 30 minutes.
- Blood (about 5 tablespoons) will be drawn for routine and research tests. The research tests in this study will be used to look for molecules that may predict your response to treatment. The blood will not be used for study purposes if you are not eligible or choose not to participate in the study.
- If you can become pregnant, part of the above blood sample or a urine sample will be collected for a pregnancy test. To take part in this study, you must not be pregnant.

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 35 participants will be enrolled in this study. All will take part at MD Anderson.

Radiation Therapy Planning and Treatment

About 3 weeks after your screening visit, you will have a CT scan and an MRI to check the status and location of the disease, including the motion of the tumor while you breathe. The study staff will use the results of these imaging scans to plan your radiation therapy. If you have a device that is MRI compatible, you may have a study visit before the MRI. The study doctor will discuss this with you.

About 2 weeks after your CT scan and MRI, you will receive radiation therapy. It will be given on 3 separate, non-consecutive weekdays. This means the shortest possible radiation therapy schedule would be treatment on a Monday, Wednesday, and Friday. Each session of radiation therapy may last at least 1-2 hours.

The study doctor will tell you on what days you will receive radiation therapy.

On your last day of radiation therapy, blood (about 5 tablespoons) will also be drawn for routine and research tests. You will also complete the financial questionnaire from the screening visit.

You will no longer be able to receive radiation therapy if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

Follow-Up

You will have follow-up visits **3, 6, 12, 18, and 24 months after your last dose of radiation therapy**. The following tests and procedures will be performed:

- You will have a physical exam.
- You will complete the financial questionnaire.
- Blood (about 5 tablespoons) will be drawn for routine tests. During the 3-month visit only, blood (about 5 tablespoons) will also be drawn for research tests.
- During all follow-up visits except for the 3-month visit, you will have imaging scans to check the status of the disease. This may include an MRI and/or a CT scan.
- During the 12-month visit only, you will have a split function renal test to check your kidney function.
- During the 24-month visit only, you will have a tumor biopsy to check the status of the disease.

Long-Term Follow-Up

After your 24-month visit, the study staff will check on how you are doing every 6 months until the end of the study. This can be done with a clinic visit, a phone call, or a review of your medical records. If called, this phone call should take about 5-10 minutes.

2. POSSIBLE 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 Risks

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

• fatigue • weakness • swelling (arms, torso, legs, genitalia) • damage to the spinal cord or nerves (possible pain, loss of strength or feeling in the legs and/or loss of bladder/rectum control) • skin changes (possible dryness, itching, peeling, and/or blistering) • hair loss at the treatment site • mouth problems • trouble swallowing • nausea • vomiting • loss of appetite	• weight loss • inflammation of the stomach or colon • damage to stomach (possible indigestion, pain, and/or bleeding) • damage to the bowel (possible intestinal blockage, abnormal connections of passageways between organs or vessels, sores, bleeding, diarrhea, or inability to process food) • diarrhea • liver damage • kidney damage • bladder inflammation (possible pain and/or urge to urine)	• damage to bladder (possible frequent urination, blood in urine, urinary infection, pain, or spasms) • urinary and/or bladder changes • sexual changes • sexual dysfunction • impotence • damage to the testicles (possible low sperm count or inability to have children) • damage to the ovaries (possible inability to have children or early menopause) • changes to the menstrual cycle • inability to produce children • joint problems • secondary cancers

While all of the risks in the above table are possible, the most likely side effect of radiation to the kidney is mild fatigue and decreased kidney function. A mild redness of the overlying skin is also possible. Although radiation to the kidney can potentially injure any nearby organs including the bowel, liver, stomach, ureter, and spinal cord, severe damage is rare.

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.

Radiation therapy may cause a low white blood cell count. A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

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.

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. Because kidney tumors tend to bleed easily, the most relevant of these risks is bleeding. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

The **split function renal test** involves a radiotracer, which will expose you to a small dose of radiation. The radiotracer dose is relatively small and similar to many other routine medical imaging tests. You may have an allergic reaction to the radiotracer. A small number of patients may need to receive the drug Lasix before their split function renal test. If you receive Lasix, there is a low risk that you may experience an allergic reaction to Lasix or decreased kidney function. If you are breast feeding, you will be advised to stop breast feeding for 2 days after this procedure.

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.

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.

This study may involve unpredictable risks to the participants.

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. You must use birth control during the study if you are sexually active.

Birth Control Specifications: Talk to your doctor about appropriate methods of birth control during this study.

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

Females: If you are pregnant, you will not be enrolled on this study, as the radiation treatment may cause harm to a fetus or unborn baby. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant before or during radiation therapy will result in your removal from 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 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. Chad Tang, at 713-792-5905) 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 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.

   The results of all imaging, including MRI scans, will be discussed with you.

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

Future Research

Data

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

Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research 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 research samples are used for future research. If future 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 research 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.

Genetic Research
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.

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

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

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

_____ _____
SIGNATURE OF LAR DATE

_____
PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2020-0168**.

_____ _____
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 DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION