IRB Approval
09-0625
This Form Valid
7/15/15 - 7/13/16

Subject Information

Consent to Participate in a Research Study

09-RAD-01: Conformal High Dose Intensity Modulated Radiation Therapy for Asymptomatic Metastatic Disease to the Thoracic and Lumbar Spine

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about using a special form of radiation therapy called stereotactic radiation therapy to treat metastatic cancer that has spread to the spinal column. You are being invited to take part in this research study because you have been diagnosed with metastatic cancer to the thoracic or lumbar spine and currently have no attributable symptoms. If you volunteer to take part in this study, you will be one of about twenty-five (25) people at the University of Kentucky to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Ronald C. McGarry, M.D., Ph.D. of University of Kentucky, Department of Radiation Medicine. There may be other people on the research team assisting at different times during the study. In particular, these will include William St. Clair, M.D., Ph.D. and Jonathan Feddock, M.D.

WHAT IS THE PURPOSE OF THIS STUDY?

By doing this study, we hope to determine if Conformal High Dose Intensity Modulated Radiation Therapy is an appropriate option for treating cancer that has spread to the spinal column. In particular, we are studying its use in patients who have been diagnosed with metastatic cancer to the thoracic and lumbar vertebral body levels and currently do not have symptoms caused from the area of concern. Data suggests that this is not only a safe form of treatment, but that it can reduce the risk of the cancer coming back in the area that we treat which may reduce the risk of developing symptoms like pain in the future. Our goal is to examine the safety and effectiveness of using Conformal High Dose Intensity Modulated Radiation Therapy for treating patients with metastatic cancer to the thoracic and lumbar vertebral body levels without symptoms. Should the cancer come back in the area that we treat, further radiation treatments may remain an option in the future. This form of treatment may not extend your life.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

Patients will not be able to take part of this study if they are under the age of 18, are currently pregnant, or have received previous radiation therapy treatments to the spine.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the University of Kentucky Markey Cancer Center. You will need to come to the Department of Radiation Medicine approximately eight times during the study. Each of those visits will take about 30 minutes. The total amount of time you will be asked to volunteer for this study is 4 hours over the next 1 year.

WHAT WILL YOU BE ASKED TO DO?

Enrolling in this study will require you to come to the Radiation Medicine clinic for 8-10 visits total.

The first visit, an initial consultation, will take approximately one hour. Time will be spent obtaining a past medical history, current review of symptoms, full physical examination, and reviewing all relevant medical reports and then determining eligibility for the study. We will also obtain consent at this time for participation. Any additional tests that are needed for your evaluation and care will be ordered. After this appointment, we will schedule a simulation session to plan your treatment.

You will be scheduled to return within a few business days to undergo your simulation session. During this visit, we will first create a special mold which will conform to your body when you lie on your back. Once this is completed, we will obtain a CT scan with you lying in the mold. This CT scan is different from others in that (1) you are required to be in the mold at the time of the scan, and (2) this scan is used to determine positioning on the treatment machine. Once the CT scan has been completed, we will need to mark your skin with two small tattoos which are required to ensure proper alignment and positioning at the time of treatment. This session usually takes up to an hour.

Approximately 5 working days later, you will return for your radiation treatment. In most cases you will have a single treatment; however, for some patients the physician may divide the radiation treatment into three sessions. The session(s) will last up to one hour. We will bring you into the treatment room, and position you in the mold that was created during the simulation session. We will use the tattoos to properly line you up with the treatment machine. After we can verify that you are in the correct physical position relative to the mold and treatment machine, we will take x-rays to confirm that everything lines up appropriately. Once these have been reviewed, your treatment will begin and will last about 45 minutes total.

The remainder of the visits will be devoted to routine follow-up visits. We will re-evaluate you 1, 3, 6, 9, and 12 months following completion of your treatment. The total time required for these visits is 15-30 minutes. You will have imaging studies (such as CT scan, PET scan, bone scan, MRI) if needed during your follow-up. After the study is over, you may continue to receive routine follow-up to monitor your condition.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- Skin erythema/redness and/or burning sensation which typically resolves following treatment
- Generalized weakness and/or fatigue which could last for several weeks
- Symptoms of nausea, vomiting, loose stool, and/or diarrhea. Typically mild, although can last for several days.
- Injury to spinal cord, which is the rare event that could lead to paralysis. The goal of this study is to spare the spinal cord from receiving as much dose of radiation as possible. This will help to

minimize the risk of spinal cord injury, the most extreme of which is paralysis. If we believe we are placing a patient at risk for spinal cord injury, the patient will not be treated.

- Esophagitis, or sore swallowing, a rare side effect, but typically can last a few weeks.
- Increased risk for compression fracture is a rare side effect from spinal irradiation.
- Radiation has been shown to cause the development of secondary cancers. These typically occur greater than 5-10 years following radiation and are exceedingly rare.

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Skin Erythema / Redness	Rarely	Usually of short duration	It will go away following treatment
Weakness and/or Fatigue	It occasionally occurs	Patients may want to nap or sleep longer at nighttime	It will go away following treatment
GI Symptoms: Nausea, vomiting, loose stool, diarrhea	It occasionally occurs	Usually of short duration	It will go away following treatment.
Spinal Cord Injury	Exceedingly rare	Very, symptoms can be irreversible	Yes, with proper treatment planning and positioning.
Esophagitis	It occasionally occurs with radiation therapy to the chest.	Usually of short duration	It will go away following treatment.
Second cancers	Exceedingly rare	Development of cancer is a major impact on overall health.	No

There is always a chance that any medical treatment can harm you, and the investigational treatment in this study is no different. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. However, some people have experienced improved control of their cancer when treated in a similar manner. Your willingness to take part, however, may, in the future, help doctors better understand and/or treat others who have your condition.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on the quality of medical care you receive.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the study, there are other choices such as:

- You may have Conformal High Dose Intensity Modulated Radiation Therapy without participating in the study.
- You may be able to participate in another study.
- You can continue to be followed with bone scans, CT scans, or MRI scans, and physical exams, and receive palliative treatment (meaning treatment aimed at controlling your symptoms) once you start having symptoms or show evidence of disease progression.
- You can choose not to get any treatment.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare or Medicaid will be responsible for the costs of all care and treatment you receive during this study. These costs are considered medically necessary and would be part of the **care you receive if you did not take p**art in this study.

Therefore, these costs will be your responsibility and your insurer may agree to pay those costs (you should ask your insurer if you have any questions regarding your insurer's willingness to pay these costs); Medicare, or Medicaid will pay medically necessary costs (if you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid at 1-800-635-2570.

A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep private all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. You should know, however, that there are some circumstances in which we may have to show your information to other people. Such circumstances might entail involving another department for assistance in the event should you develop symptoms or problems that will require another physician's assistance or help in treating. Also, in certain instances, the law may require us to show your information to a court or to tell authorities if you report information about a child being abused or if you pose a danger to yourself or someone else.

Officials of the University of Kentucky and the Markey Cancer Center may look at or copy pertinent portions of records that identify you.

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CAN YOUR TAKING PART IN THE STUDY END EARLY?

The study is evaluating a single treatment, so the decision is primarily to receive the treatment or not. Although the follow-up visits are very important in not only monitoring for side effects but also for determining the effectiveness of the radiation treatment; should you decide not to continue the trial at any point, you will not be treated any differently. You will have the right to decide at any time that you no longer want to continue.

The individuals conducting the study may need to withdraw you from the study if the primary investigator determines that you are unable to complete the treatment, however this will not prevent you from being able to be treated in a similar fashion. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the University of Kentucky decides to stop the study early for a variety of scientific reasons.

In order to determine if your cancer is progressing or responding to treatment, you must be evaluated on multiple occasions which allow us to obtain bone scans which can be compared to previous scans. In addition, radiation therapy can cause multiple side effects, and the follow-up visits allow for the opportunity to evaluate and treat any problems you might be having as a result of the radiation treatments.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may be able to receive the treatment portion of this trial if you are currently involved in another research study. You may enroll in another clinic trial if it does not overlap with these dates. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call the University of Kentucky Radiation Medicine Clinic and ask to speak with Dr. Ronald McGarry at 859-323-6487. If it is after normal working hours or on the week-end call 859-323-5321 and speak to the Radiation Oncologist on call.

Dr. Ronald McGarry will determine what type of treatment, if any, that is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs that result from research related harm cannot be included as regular medical costs. Therefore, the medical costs related to your care and treatment because of research related harm will be your responsibility. If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.

A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs).

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Dr. Ronald McGarry at 859-323-6487. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WHAT ELSE DO YOU NEED TO KNOW?

There are no financial disclosures. This is a study being conducted only at the University of Kentucky.

You will be told if any new information is learned which may affect your condition or influence your willingness to continue taking part in this study.

You will receive a copy of this form. If you want more information about this study, ask your study doctor.

You have read it or it has been read to you. You understand the information and have had your questions answered. You agree to take part in this study.

_____ _____

Signature of person agreeing to take part in the study Date

_____

Printed name of person agreeing to take part in the study

_____ _____

Name of [authorized] person obtaining informed consent Date

_____

Signature of Investigator