UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH

EFFECTS OF RADIATION THERAPY BEFORE SURGERY FOR TREATMENT OF PROSTATE CANCER

Technical Title: Phase I Trial of Preoperative Adjuvant Stereotactic Body Radiotherapy for Patients at High Risk of Local Failure after Prostatectomy

INTRODUCTION

Nicholas Nickols, MD, PhD, Christopher King, MD, PhD, Amar Kishan, M.D., Albert J. Chang, M.D., and Michael Steinberg, MD from the Department of Radiation Oncology and Robert Reiter, MD from the Department of Urology at the University of California, Los Angeles is conducting a research study.

The researchers will explain this study to you. **Research studies are voluntary and include only people who choose to take part.** Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

WHY IS THIS STUDY BEING DONE?

Prostate cancer is the most common non-cutaneous male cancer diagnosed in the United States. Previous research shows that some patients who undergo prostatectomy (removal of the prostate) have an increased risk of tumor recurrence (return of your cancer after treatment) as compared to patients who undergo prostatectomy and radiation. Improving cancer care for localized prostate cancer that is at high risk for recurrence is therefore important and likely to reduce mortality.

Recent studies suggest the use of adjuvant therapies (additional treatment for your cancer) may offer an advantage in reducing the amount of radiation required, while improving survival. The goal of this study is to find out if adjuvant radiotherapy given before your surgery can improve rates of survival and perhaps reduce the side effects typically experienced by patients like you.

The research team is asking you to be in this study because you have recently decided to undergo radical prostatectomy (surgical removal of the prostate) for the treatment of your prostate cancer.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

12 people will take part in this study at UCLA Medical Center, the only site participating in this study.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Prior to Enrollment:
You will be seen in the Radiation Oncology clinic by one of the study investigators. The study objectives and procedures will be explained to you. If you wish to participate, we will ask you to sign a written informed consent form. The research team will determine your eligibility for enrollment; review your medical history and previous procedures. If the exams, tests and/or procedures show that you are eligible for this study, we will ask you to complete the following:

Prior to Treatment:
You will be asked to undergo a research blood draw (up to 8 teaspoons), which will be stored for future use. This is in order for the researchers to determine if there is a substance in your blood (biomarker) that predicts your response to therapy and side effects. In addition, we will perform functional imaging of your tumor before treatment using a CT scan. This scan is routine for patients like you who will receive radiation therapy and you would be asked to have this scan even if you were not participating in this study. This mapping scan also helps the investigators optimally plan your radiation treatments. It will be done after a custom plastic mold is made to help immobilize your back, chest and abdomen during the scan and for each treatment. After the scan, your physicians along with physicists will use computers to map and customize the radiation therapy that will best treat the tumor and spare your normal tissue.

A bone scan will also be performed to rule out metastasis (cancer that spreads to a different part of the body from where it started). A bone scan is a nuclear medicine test that uses a very small amount of a radioactive substance, called a tracer, injected into a vein that shows possible cancer in areas where too much or too little tracer has been absorbed by the body. This scan is routine for patients like you who will receive radiation therapy and you would be asked to have this scan even if you were not participating in this study.

During the Study:
Once the radiation mapping procedure is completed, radiation therapy will begin. Prior to surgery, you will receive radiation therapy delivered in three sessions. These sessions will occur on Monday, Wednesday and Friday and will last approximately one hour. On the last session of your radiation therapy, a research blood draw (up to 8 teaspoons) will be performed. Your planned surgery (prostatectomy) will then be scheduled to occur within 4 weeks of completing radiation therapy. Some of the tissue taken during prostatectomy will be used for research purposes.

After the Study (Follow-Up):
Following completion of your surgery, you will be expected to follow-up with your study physician on a regular basis. We will ask you to undergo the following exams and procedures as part of your follow-up visits:

<u>Every 3 months for 1 year</u>:

- Blood draw (up to 8 teaspoons of blood)

- Evaluation of any side effects you may be having
- Complete a written questionnaire to assess your quality of life and response to treatment

HOW LONG WILL I BE IN THIS STUDY?

Following completion of your treatment, the researchers will ask you to remain enrolled in this study for one year. The researchers will ask that you come in for follow-up visits every three months for the duration of the one year period.

If you wish to transfer your care to another physician during this time while you are still enrolled on the study, we ask that further follow-up information be sent to us by your physician.

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?

Known risks and discomforts:
There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the study doctor if you have any questions. Cancer treatments often have side effects. The treatment used in this program may cause all, some or none of the side effects listed. In addition, there is always the risk of very uncommon or previously unknown side effects occurring.

Risks of Radiation Exposure Associated with Radiation Therapy:

Since the radiation procedures are considered standard of care, the amount of radiation you will receive is equivalent to the radiation that would be used for similar patients who are not participating in this study. Therefore, you will not be exposed to any additional radiation by participating in this study.

During the process of treatment planning and radiation, you will lie in a specific position, possibly within a frame device, and some patients can become claustrophobic. Medications can be given to make you feel more comfortable should this happen. Also, your study doctor may give you pain medication before each treatment to decrease any discomfort you may have due to lying on a hard surface and/or due to lying with your arms held above your head during the treatment.

Risks of blood draw:
Approximately 8 teaspoons of blood will be drawn before, during and after treatment for research purposes. Whenever possible, these samples will be obtained at the same time as other routine laboratory studies to minimize the number of blood draws. There are minimal risks associated with this procedure. They include: (1) minor discomfort, (2) bleeding or bruising at the site of blood draw, (3) small risk of infection, (4) rare cases of fainting. If you have ever fainted during a blood draw, please let your study physician know.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to me:
We cannot guarantee that you will receive any benefit from participating in this study. The information obtained from this study will help researchers learn more about the effectiveness of pre-surgery radiotherapy to treat patients with prostate cancer in the future.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to take part in this study, or if you withdraw from this study before it is completed, you may choose to undergo the standard prostatectomy without the use of additional therapies.

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers or the study sponsor might also decide to stop the study at any time.

If you are thinking about stopping the study for any reason, it is important to tell your study doctor so that any risks from the treatment can be evaluated. Your study doctor will also be able to discuss any recommendations for follow-up care.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

How information about you will be stored:
Information related to your participation in this study will be entered into a secured electronic database. Those documents will be kept under control of the study team at all times.

People and agencies that will have access to your information:
The research team, authorized UCLA personnel, and regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

How long information from the study will be kept:
Information will be kept for a minimum of five years, or two years after the study is closed, whichever period is longer.

The National Cancer Institute's (NCI) Clinical Trials Reporting Program (CTRP) is a comprehensive database of information about all NCI-supported clinical trials. The goal of this comprehensive database is to help NCI identify areas that need more clinical research and to help NCI decide which studies are most important to do first. The NCI requires that cancer clinical trials report information about how many subjects are enrolled in the trials and the outcome of the trials. Specific information about you as a subject will be included in the database. This information will include information about your cancer, your study identification number, the month and year of your birth, as well as your gender, country of origin, race, ethnicity, and zip code. This information will be maintained in a secure and confidential manner by the NCI CTRP in their electronic database. The NCI CTRP has many safeguards in place for privacy, security, and limited authorized access.

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?

The study will pay for research-related blood draws that are provided only because you are participating in this study. You or your health plan may be responsible to pay for all the types of items listed below:

- Items and services that would have been provided to you even if you were not in this study
- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Deductibles or co-pays for these items and/or services

You will also be responsible for paying the cost of parking during your scheduled visits to UCLA Radiation Oncology. Although you will be participating in this research study, you would have received radiation therapy otherwise and thus would have incurred parking costs regardless of your participation in the study.

You will not be responsible for the cost of any research blood draws.

WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid for your participation in this research study. You will not be reimbursed for any out of pocket expenses, such as parking. The cost of parking at UCLA Medical Center while receiving treatment is a cost you would have been responsible for paying whether or not you were enrolled onto this study.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:
You may contact Dr. Nicholas Nickols and any of the investigators from Radiation Oncology at (310)825-9775 or you may contact Dr. Robert Reiter with the department of Urology at (310)794-7224 with any questions or concerns about the research or your participation in this study. You can also call the UCLA Page Operator at (310) 825-6301 to reach Dr. Nickols or any of the additional study doctors 24 hours a day, 7 days week.

UCLA Office of the Human Research Protection Program (OHRPP):
If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone: (310) 825-5344; by email: mirb@research.ucla.edu or U.S. mail: UCLA OHRPP, 10889 Wilshire Blvd, Suite 830 Los Angeles, California 90095-1694.

Public Information about this Study:
ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?
Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at anytime.

- If you decide to stop being in this study you should notify the research team right away. The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still get medical care from UCLA.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

SIGNATURE OF THE PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____
Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

STUDY CALENDAR

Procedure	Pre-Study	Pre-SBRT	SBRT	0-4 weeks post SBRT	Within 4 weeks of final SBRT	3 Month Follow-up (± 4wks)	6 Month Follow-up (± 4wks)	9 Month Follow-up (± 4wks)	12 Month Follow-up (± 4wks)
Informed Consent	X								
Medical History	X								
Translational Research Blood Draw[1]		X		X		X	X		
Radiation Treatment			3 fxs within 1-2 weeks						
Prostatectomy					X				
EPIC Questionnaire	X			X		X	X	X	X
IPSS Questionnaire	X			X		X	X	X	X
Side Effects Evaluation	X			X		X	X	X	X
CT or MRI of Abdomen/Pelvis (within 120 days prior to registration) or PSMA PET/CT[3]	X[2]								
Bone scan (within 120 days prior to registration)	X[2]								
Treatment Planning scan		X							
Follow-up visit						X	X	X	X

1 *Translational Research blood draw will consist of 5 x 10 ml EDTA lavender top tubes, 1 x 5 ml gold top tube and 1 x 5 ml CTAD blue top tube (a total of approximately 60 mLs)*
2 *To verify no distant metastases, the subject must have CT or MRI of the abdomen/pelvis and a bone scan within 120 days prior to registration. If the bone scan is suspicious, a plain x-ray or MRI must be obtained to rule out metastasis.*
3 *CT/MRI scan of Abdomen/Pelvis is not required if patient gets PSMA PET scan*