Official Title: A Phase I/II study of salvage high-dose-rate Brachytherapy, ExternAl beam COmbined and short-term hormonal therapy for the treatment of Node-positive locally recurrent prostate cancer after prior definitive radiotherapy.

NCT Number: NCT03553602

IRB NUMBER: 210546120817

LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES DIVISION
MAYWOOD, ILLINOIS
DEPARTMENT OF

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE: BEACON – A phase I/II study of high-dose-rate Brachytherapy and External beam and short-term Androgen deprivation COmbined for the treatment of Men with Fluciclovine PET Pelvic Nodal Uptake in locally recurrent prostate cancer after prior definitive radiotherapy

THE APPROVAL FOR THIS PROJECT EXPIRES ON 11/15/2024.

Participant Information

PRINCIPLES CONCERNING RESEARCH: You are being asked to take part in a research project. It is important that you read and understand the principles that apply to all individuals who agree to participate in the research project described below:

1. Taking part in the research is entirely voluntary.

2. We do not know if you will benefit from taking part in the research but the knowledge obtained may help others.

3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

4. If during your participation in the research project new information becomes available which would affect your being in the research project (such as better treatments or the side effects of the treatments), your doctor will discuss this new information with you and will help you make a decision about your continuing in the research.

The purpose of the research, how it is to be done, and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

PURPOSE OF RESEARCH: You are being asked to participate in this study because

you have prostate cancer that has come back in your prostate after being treated with prior radiation therapy, and a fluciclovine PET scan shows suspicious lymph nodes in your pelvis.

This purpose of this study is to evaluate the safety and effectiveness of a technique called high-dose-rate (HDR) brachytherapy with external beam radiotherapy to the pelvis and 6 months hormonal therapy as treatment for prostate cancer that has come back in the prostate after prior radiotherapy. The study will examine the side effects of the treatment as well as the ability of the treatment to get rid of the cancer. This involves the placement of a radioactive material in the affected area of the prostate temporarily, where it remains for a short period of time, and then is subsequently removed using a minimally invasive technique described below. You also will receive external radiation for 5-8 weeks targeting the pelvis and giving a higher dose each day to the suspicious lymph nodes on the PET scan.

This research is sponsored by Loyola University Medical Center

Approximately 24 people will participate in this research.

DESCRIPTION AND EXPLANATION OF PROCEDURES: If you agree to participate in this study, you will need a physical exam including a digital rectal exam, a PSA blood test, a standard prostate biopsy. You will also need at least a bone scan, CT abdomen/pelvis or MRI of your pelvis, and a fluciclovine PET scan to verify there is no disease that has spread outside of the pelvis. Your doctor may recommend other imaging studies as well, which will be discussed with you.

Because part of the treatment is an invasive procedure, you will also need medical and/or cardiac clearance for the use of general anesthesia, which may include EKG, chest x-ray, labs, and/or additional tests as deemed necessary by our anesthesia department.

The treatment consists of multiple components. A temporary implant that will be inserted into your prostate and radiation treatment will be given via the implant. The procedure where the implant is performed will be done under general anesthesia or anesthesia injected into the spinal canal to numb the lower part of the body. While under anesthesia, certain additional procedures may be performed to evaluate and ensure the implant placement, including cystoscopy (looking in the bladder with a small flexible camera) and transrectal ultrasound. The actual implant procedure is as follows: After placement of a foley catheter in your bladder, under the guidance of ultrasound, thin catheters will be inserted through the skin between the anus and scrotum into the prostate. A marker may be placed in the target area which will remain in that area permanently. Once the implant is complete, you will be awoken and the breathing tube will be removed and you will be transferred to recovery. In recovery, you will receive medications to help with any pain you are having. Following recovery, you will come to the radiation oncology department where a radiation planning CT scan of your pelvis will be done to identify the location of the catheters, the prostate and normal structures. There may be small adjustments of the implant catheters to fine-tune the exact position of your implant at this time. After we confirm the areas of disease where the radiation will be delivered and design your brachytherapy plan, you will be taken to our brachytherapy treatment room, where a radioactive source will be

guided through the catheters, delivering radiation to the defined areas. The treatment delivery time usually takes 20-30 minutes. After the treatment is completed, the radiation source is moved back in the treatment machine and you are not radioactive. After the treatment process is complete, all implant catheters and foley catheter will be removed. You will be discharged after this.

You will also receive external beam radiotherapy, starting either before or after the brachytherapy treatment. For this, you will undergo a CT simulation, which is an appointment where you will come in and have a custom mold created to lay on, and have possible small tattoos placed on your body to help with daily set up. Then a CT scan will be performed and used by your treating doctor to create a radiation plan. Then, after about 1-2 weeks, you will start daily radiation treatments for 5-7 weeks, Monday through Friday.

You will also receive hormone therapy for at least 6 months. This will include an injection that you receive every 3-6 months for the total duration, and a pill you will take daily until the end of the external beam radiotherapy.

You will also be asked to complete 2 short questionnaires regarding your urinary, bowel and sexual function and quality of life. These questionnaires will be completed before you receive your radiation treatment and then at each follow-up appointment.

Your radiation oncologist will be performing the brachytherapy implant procedure, possibly with the aid of a urologist, and will be designing and delivering the brachytherapy and external beam radiation. Following the treatment you will see the radiation oncologist at 1 month, 3 months, 6 months and 12 months after treatment. Then you will see the doctor every 6 months for 4 more years, and then annually thereafter. Your doctor will order PSA blood tests, perform physical exams including digital rectal exams, and any further tests as deemed necessary.

A description of this clinical trial will be available at *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.

RISKS/DISCOMFORTS: You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects, both during the procedure and with follow-up. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Most side effects go away within a few months of the study treatments. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death, however this risk is very low.

You should talk to your study doctor about any side effects that you have while taking part in the study.

The brachytherapy implant is done with anesthesia. Risks and side effects related to the anesthesia incluse those that are:
Likely:

- Nausea
- Vomiting
- Headache
- Sore throat
- Pain with urination
- Pain with bowel movements
- Pain in the perineum

Less Likely, but serious

- Damage to teeth

Rare but serious:

- Blood pressure or heart rhythm problems
- Problems breathing
- Heart attack
- Allergic reaction
- Stroke
- Death

The brachytherapy implant is a minimally invasive procedure with risks unrelated to the actual radiation delivery:

Likely:

- Soreness in the implant area
- Infection that can be treated with antibiotics
- Bladder irritation with bleeding in the urine

Less Likely, but serious:

- Need for use of a urinary catheter for a temporary or an indefinite duration after the implant procedure due to urinary retention or obstruction
- Injury to the bladder, urethra, or other tissues in the pelvis or abdomen
- Rectal bleeding
- Serious infection

There are risks associated with the radiation delivered with brachytherapy and external beam radiotherapy:

Likely:

- Weak/slow stream of urine
- Frequent urination both during the day and night
- Strong urges to urinate
- Pain or discomfort with urination
- Erectile dysfunction which can be permanent
- Diarrhea
- Abdominal discomfort
- Gassiness

These problems are common, but they may improve or go away with time or the use of medicines.

Less Likely:

- Inability to urinate (urinary retention), possibly requiring temporary or permanent urinary catheter placement
- Leakage of urine (incontinence)
- Diarrhea
- Rectal bleeding
- Blood in the urine

Rare, but serious:

- Damage to the urethra or rectum requiring surgery
- Damage to the bladder, bowel, or other tissues in pelvis requiring surgery
- Urinary obstruction requiring surgery

Risks and side effects related to the *hormone therapy* include those which are:

Likely

- Hot flashes
- Erectile dysfunction
- Loss of libido
- Mild fatigue
- Breast tenderness or mild enlargement
- Diarrhea

Less Likely

- Headaches
- Bone/joint pain
- Liver toxicity (detected on a blood test) requiring reduced dose or stopping treatment
- Severe fatigue
- Skin rash/hives
- Swelling
- Decrease in bone mineral density
- There may be increased risk of rectal or bladder side effects as a result of the interaction between the hormone therapy and the external beam radiation therapy.

Rare, But Serious

- Severe allergic reaction
- Increased long-term risk of cardiovascular disease
- Increased long-term risk of developing diabetes

REPRODUCTIVE AND SEXUAL ACTIVITY INFORMATION: The intervention in this study may cause sterility

BENEFITS: We do not know if you will benefit from participating in this study. The information learned may help others in the future.

ALTERNATIVE TREATMENTS: You do not have to participate in this research project to receive care and treatment at Loyola University Medical Center.

Your doctor has discussed other options with you along with their risks and benefits.

FINANCIAL INFORMATION: Some health plans will not pay the costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting treatment without being in this study. Depending on your health insurance, there may be a co-payment for the standard visits. You will be responsible for any usual out-of-pocket expenses such as co pays, coinsurance or deductibles.

RESEARCH RELATED INJURY: In the event that you are injured or have side effects as a result of participating in this research project, your doctor will take the necessary steps to treat the problem. There are no funds available from Loyola University Medical Center, Loyola University Health System or Loyola University Chicago to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems. By signing this form, you are not giving up any legal rights to seek to obtain compensation of injury.

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, your test results, and how you do from you and your Loyola University Medical Center (LUMC) medical records. The information will be collected by the study physician(s), the research nurses, data administrators and secretaries.

Information about you will be provided to Loyola University Chicago; the research sponsor; data collection and study verification agencies; and/or government regulatory agencies such as the Food and Drug Administration.

In this way, we will learn about the safety and effectiveness of a technique called high-dose-rate (HDR) brachytherapy with external beam radiotherapy to the pelvis and 6 months hormonal therapy as treatment for prostate cancer that has come back in the prostate after prior radiotherapy.

The information we will collect and send includes:

__X__ DEMOGRAPHIC INFORMATION (e.g., name, address, phone number, Social Security Number)

__X__ MEDICAL RECORD (including, but not limited to, history and physical exam notes, progress notes, consultation reports, laboratory test results, AND/OR operative reports)

__X__ PHOTOGRAPHS, VIDEOTAPES, OR DIGITAL OR OTHER RADIOGRAPHIC IMAGES

We will collect and provide this information about you for as long as you are in the study.

Once the information is disclosed outside of LUMC, it may no longer be protected by federal privacy laws.

It is possible that the sponsor, research nurses, data collection and/or study verification agencies, data administrators or staff, or the Food and Drug Administration will come to LUMC and view the medical record (see above for description of content) and the research records. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information LUMC is sending to them.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUMC to use and disclose your medical information is required in order for you to participate in the study.

WITHDRAWAL OF CONSENT: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent for LUMC to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at LUMC unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by LUMC and the sponsor.

For your safety, we may ask that you return to clinic one more time for follow up. If you withdraw from the study, you will need to contact your physician(s) to discuss what other options may be available.

If you withdraw from the study, we will ask that you sign the form attached to this consent and send it to Dr. Solanki or give it to the study staff. Your withdrawal from the study will not have any affect on any actions by LUMC taken before the attached form is received by LUMC.

Your study doctor, the Institutional Review Board, the regulatory authorities, or the sponsor, may terminate the study at any time with or without your consent.

Your study doctor may choose to take you out of the study because of unexpected or serious side effects or treatment non-compliance,. You may also be removed from the study if your study doctor feels that you are not benefiting from the study treatment.

CONSENT

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-216-4608.

_____Date:____/_____/____

Signature

Dr. Solanki, the principal investigator for this study, or his associates will be available to answer any questions you may have. Dr. Solanki can be reached at: 708-216-4608.

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact either Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Division, at 708-216-2633 or Cynthia Tom-Klebba, MA, Director of the Human Research Subjects Protection Program at 708-216-4608.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

PROJECT TITLE: "A Phase I/II study of salvage high-dose-rate Brachytherapy, ExternAl beam COmbined and short-term hormonal therapy for the treatment of Node-positive locally recurrent prostate cancer after prior definitive radiotherapy"

REVOCATION OF AUTHORIZATION TO
RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the study titled, "A Phase I/II study of salvage high-dose-rate Brachytherapy, ExternAl beam COmbined and short-term hormonal therapy for the treatment of Node-positive locally recurrent prostate cancer after prior definitive radiotherapy", at Loyola University Medical Center ("LUMC"). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information to Dr. Abhishek Solanki as outlined on the consent form, which I signed on ____/_____/____ (INSERT DATE CONSENT WAS SIGNED ORIGINALLY). I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

_____Date:____/_____/____
Signature: Participant

Please return this form to:

Abhishek Solanki, MD
Radiation Oncology Department
Loyola University Medical Center
2160 South First Avenue
Maywood, Illinois 60153