MC1754 / 17-009199

A Phase II Trial of Hypofractionated Radiation Therapy for Prostate Cancer with High Risk Features after Radical Prostatectomy

NCT03570827

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MAYO CLINIC

Name and Clinic Number

Approval Date: **March 5, 2020**
Not to be used after: **March 4, 2021**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: A Phase II Trial of hypofractionated Radiation therapy for prostate cancer with high risk features after radical prostatectomy

IRB#: 17-009199

Principal Investigator: Carlos Vargas, MD and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigators: Carlos Vargas, MD (Arizona) Bradley Stish, MD (Rochester)	**Phone:** [redacted] **Institution Name and Address:** Mayo Clinic 5777 E. Mayo Boulevard Phoenix, AZ 85054 **Phone:** [redacted] **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate **(The RSA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Patient Account Services	**Toll-Free:** (844) 217-9591	▪ Billing or insurance related to this research study

Other Information:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. It will also be available on http://www.mayo.edu/research/clinical-trials. These Websites 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.

1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because your prostate cancer was found to have high risk features after your surgery and due to the slow growth seen with your type of prostate cancer you may benefit from a shorter radiation treatment.

This study is being conducted at Mayo Clinic centers in the United States. The plan is to have about 62 people take part in this study at Mayo Clinic.

2. Why is this research study being done?

The purpose of this study is to compare the effects of a shorter course of radiation therapy (5 treatments over 2 weeks) with a higher daily dose of radiation, to the current course of a lower dose over 6-7 weeks, to see if the effects of the treatments are similar or better.

One of the standard treatment options for your type of prostate cancer is external beam radiation therapy using x-rays or protons. Recent studies have shown improved disease control when higher daily doses of radiation are given. This treatment change is investigational which means it has not been approved as a standard of care treatment.

3. Information you should know

Who is Funding the Study?

Mayo Clinic benefactor funds will cover the costs related to running this study.

Therapeutic Misconception?

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

4. How long will you be in this research study?

Your treatment may last for up to 2 weeks; however, long term follow up will be for life.

5. What will happen to you while you are in this research study?

Screening/Pre-Treatment
During the screening visit, we will do some tests and procedures to see if you are eligible to take part in this research study. The Principal Investigator will review the results of these tests and procedures. If you aren't eligible, the Principal Investigator will tell you why. At this visit we will:

- History and physical exam, including a digital rectal exam (DRE) and an assessment of your ability to carry out activities of daily living (which will include questions such as whether you are able to feed, bathe, and dress yourself)
- Evaluation of the pathology of the surgery (this information helps determine the risk factors of your prostate cancer)
- Blood tests to determine your PSA levels (values that help determine the stage of your prostate cancer). About 3 teaspoons of blood will be drawn from a vein or, if you have one, a catheter. The study doctor may also test your testosterone.
- A CT (Computed Tomography) scan or MRI (Magnetic Resonance Imaging) of your pelvis and possibly other locations, if needed, to check for disease. An additional CT/MRI will be needed to plan your radiation treatment. CT produces a picture of your body using radiation and MRI uses a magnetic field to produce an image.
- A PET scan (Positron Emitted Tomography) of your pelvis and possibly other locations, if needed, to check for disease. A PET scan produces a picture of your body using radiation to produce an image. It helps to identify potential cancer areas.
- Bone scan, if needed
- Placement of markers and possibly a location device in your prostate fossa: under ultrasound guidance the physician will place three to four small markers, the size of a grain of rice, in the area were your prostate gland was removed.
- Other imaging studies may also be done to plan your radiation and/or assess your disease status. Your study doctor will decide with you what other studies need to be done.

You will also complete a questionnaire about your quality of life just prior to starting treatment and at every follow-up visit after receiving treatment. We hope that you will answer all of the questions, but you can skip any question that you don't want to answer. The questionnaire should take about 10-20 minutes to complete.

Treatment

If you are eligible to participate in the study, you will need the following tests and procedures. These tests and procedures are part of regular cancer care.

- History and physical exam, including an assessment of your ability to carry out activities of daily living (weekly during radiation treatment). You will need this assessment to see how the study is affecting your body.
- Assessment of any side effects that you may be experiencing from the treatment (weekly during treatment).
- CT/MRI and/or other imaging to check for treatment location weekly or as needed.

You will be "assigned" to one of the three study groups described below. Assigned means that you are put into a group based on your risk factors. Neither you nor your study doctor can choose the group you will be in.

If you are in group 1:

You will receive radiation treatments to the prostate bed. You will receive radiation therapy every other day, over 2 weeks, for a total of 5 treatments. Each radiation treatment will take 15-30 minutes.

If you are in group 2:

You will receive radiation treatments to the prostate bed. You will receive radiation therapy every other day, over 2 weeks, for a total of 5 treatments. Each radiation treatment will take 15-30 minutes. You will also receive hormone shots for up to 6 months. The hormone therapy will begin 8 to 10 weeks before the start of the radiation treatments. You will take injections either under the skin or in the muscle. There are choices as to which drug you would be given. Your study doctor will discuss in detail with you which drug to give you and how it will be given.

If you are in group 3:

You will have the areas identified to have cancer treated with radiation treatment. You will receive radiation therapy every other day, over 1- 2 weeks, for a total of 1-5 treatments. Each radiation treatment will take 15-30 minutes. You will also receive hormone shots for up to 18 months.

Note: In groups 2 and 3, you may also receive a hormone shot. The duration and use of androgen suppression will be determined by your doctor based on the risk features of your cancer.

Follow-Up Post Radiation
We request you return for follow-up visits on the following schedule after radiation treatment has ended: at 3 months, 12 months, and then yearly thereafter up to year 5. Then every 2 years with no stop date.
You will need these tests and procedures:

- History and physical exam, including a digital rectal exam (DRE), assessment of any side effects that you may be experiencing from the treatment and an assessment of your ability to carry out activities of daily living. Preferably just before your study doctor's visit.
- CT or MRI to check for disease as needed.

Note: If your disease progresses, your study doctor may request a needle biopsy of your site of failure to assess response to treatment. This biopsy would be part of your standard of care.

6. What are the possible risks or discomforts from being in this research study?

Risks and side effects related to the radiation include those which are:

Likely *(These side effects occur in 10% or more of patients)*:

- Tanning, redness, or darkening of skin in treatment area
- Temporary hair loss in the treatment area
- Bladder irritation with a stinging sensation
- Frequency or urgency of urination

Less Likely *(These side effects occur in 3-9% of patients)*:

- Urinary obstruction requiring the placement of a temporary urinary catheter
- Temporary fatigue, nausea or diarrhea
- Rectal irritation with more frequent bowel movements
- Abdominal cramps
- Rectal bleeding that does not require surgical treatment

Very Rare but Serious *(These side effects occur in less than 3% of patients)*:

- Injury to the bladder, urethra, bowel, or other tissues in the pelvis or abdomen
- Intestinal or urinary obstruction
- Inability to achieve an erection (inability of the penis to become hard)
- Rectal bleeding that requires medication or surgery to stop

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

Likely *(These side effects occur in 10% or more of patients)*:

- Hot flashes
- Temporary inability to achieve an erection (inability of the penis to become hard)
- Temporary loss of sex drive
- Mood swings
- Muscle loss, weakness, and fatigue
- Weight gain

Less Likely *(These side effects occur in 3-9% of patients)*:

- Weakening of bone (osteoporosis)
- Mild/significant anemia (drop in red blood cell count)
- Ankle swelling (edema)
- Breast enlargement and tenderness

Blood Draw Risks
The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

Biopsy Risks
The risks of biopsies can include: pain and discomfort, bleeding, tenderness, and scarring at the biopsy site. Rarely, an infection can occur at the biopsy site.

Standard of Care Risks
Your doctor will discuss the risks of all tests and procedures as these tests and procedures are part of your standard clinical care.

Unknown Risks
Many side effects go away shortly after the radiation is stopped, but in some cases side effects can be serious, long lasting, or may never go away. There may be side effects that are not known at this time.

For more information about risks and side effects, ask your study doctor.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the study doctor if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the study doctor, the study principal investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped,

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used. We will tell you about any new information that may affect your willingness to stay in the research study.

8. What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

9. What are the possible benefits from being in this research study?

Taking part in this study may or may not make your health better. The results of this study may help people with prostate cancer in the future.

10. What alternative do you have if you choose not to participate in this research study?

You don't have to be in this study to receive treatment for your condition. Your other choices may include:

- External radiation therapy using photons or protons outside of the study
- Hormone therapy
- Taking part in another study
- Getting no treatment (Although your disease may continue to grow)

Talk to your doctor about your choices before you decide if you will take part in this study.

11. What tests or procedures will you need to pay for if you take part in this research study?

You and/or your insurance will need to pay for all tests and procedures needed for your routine clinical care. You and/or your insurance may also have to pay for other drugs or treatment given to control side effects. Before you take part in this study, you should call your insurer to find out if the cost of these tests and/or procedures will be covered. Some insurers will not pay for these costs.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the "Contact Information" section of this form.

12. Will you be paid for taking part in this research study?

You will not be paid for taking part in this study.

13. What will happen to your samples?

No samples will be collected in this study.

14. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

To protect the data and confidentiality of your data, a code will be used as an identifier. The code will be a registration number assigned specifically to you by the Mayo Clinic Cancer Center Registration Office or Study Sponsor, if applicable. The correlating Mayo Clinic number and your name for reference will be maintained in a secure database accessible by Mayo Clinic assigned research staff.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

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Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

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You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

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ENROLLMENT AND PERMISSION SIGNATURES

Your signature documents your permission to take part in this research.

Printed Name | Date (mm/dd/yyyy) | Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name | Date (mm/dd/yyyy) | Time (hh:mm am/pm)

Signature