MC1651 / 15-009528

Prospective Evaluation of Hypofractionation Proton Beam Therapy with Concurrent Treatment of the Prostate and Pelvic Nodes for Clinically Localized, Intermediate or High Risk Prostate Cancer

NCT02874014

Document Date: 07/13/2018

MAYO CLINIC

Name and Clinic Number

Approval Date: **July 13, 2018**
Not to be used after: **July 12, 2019**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC1651: A Prospective Study of Hypofractionation Proton Beam Therapy with Concurrent Treatment of the Prostate and Pelvic Nodes for Clinically Localized, Intermediate or High Risk Prostate Cancer

IRB#: 15-009528

Principal Investigator: Dr. Richard Choo 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 Investigator(s): Richard Choo, M.D. William Wong, M.D. **Study Team Contact:** Rochester: Adam Amundson Arizona: Mindy Garcia, CCRP	**Phone:** (507) 284-3551 (480) 342-4800 **Phone:** (507) 293-1826 **Mayo Clinic Rochester** 200 First Street SW Rochester, MN 55905 **Phone:** (480) 342-3621 **Mayo Clinic Arizona** 13400 East Shea Boulevard Scottsdale, AZ 85259	▪ 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
Research Billing	**Rochester, MN:** (507) 266-5670 **Arizona:** (800) 603-0558	▪ Billing or insurance related to this research study

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Other Information:

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.

A description of this research study will also be available on http://www.mayo.edu/research/clinical-trials?_ga=1.25502715.752922363.1409934783. This website will not include information that can identify you. 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 you have been diagnosed with prostate cancer and you have the option of receiving proton beam radiotherapy in a shorter treatment schedule.

2. Why is this research study being done?

The purpose of this study is to find out more about the side effects of a new proton beam treatment regimen of 25 treatments and if it is the same or better than the current standard treatment regimen of 39 - 44 treatments.

The total radiation dose of 25 treatments (delivering a higher dose per each treatment) is biologically equal or very similar to 39 – 44 treatments. However, the duration of 25 treatments (5 weeks) is much shorter than that of more standard 39 – 44 treatments (7.8 weeks – 8.8 weeks). The 25-treatment regimen has been shown effective and safe with regular radiotherapy. What is new in this research study is the use of proton beam radiotherapy, instead of regular radiotherapy. Because proton beam has more favorable dose-delivery characteristics, it is expected that the use of proton beam in the 25-treatment regimen will be at least equally safe or safer than regular radiotherapy.

We hope the information from this study will help us develop a better treatment for prostate cancer that is effective and safe, but more cost saving and more convenient to patients with a shorter treatment time.

3. Information you should know

Who is Funding the Study?

The Department of Radiation Oncology is funding the study.

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

You will be in the study for 5 years. This includes the time of radiation and the follow-up period.

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

You may need to have the following exams, tests or procedures to find out if you can be in the study:

- History and Physical exam
- PSA (prostate specific antigen) and serum total testosterone blood tests
- Other blood tests as part of your regular medical care
- Questionnaires
- CT (computerized tomography) scan or MRI (magnetic resonance imaging)
- Bone Scan

These exams, tests or procedures are part of regular clinical care and usually done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your doctor.

If you are eligible and agree to be in the study, you will be asked to participate in the following:

During radiotherapy:

- Weekly symptom assessments

At the end of radiotherapy:

- Symptom assessment
- Questionnaires

Follow-up after radiotherapy: 3 months after radiotherapy, 6 months after radiotherapy, and then every 6 months up to 5 years. Note: many of the tests or procedures are part of regular clinical care:

- History and Physical exam
- PSA test
- Symptom assessment
- Questionnaires
- Serum total testosterone (this will be performed only once a year, up to 5 years)
- Blood tests, if medically indicated
- CT or MRI, if medically indicated
- Bone scan, if medically indicated

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

Risks and side effects related to proton beam therapy

Likely:

- Mild tiredness
- Increased frequency of bowel movements (diarrhea) and/or loose stool
- Urgency to have bowel movement
- Increased urinary frequency or urgency
- Mild burning or discomfort with urination
- Infertility

Less Likely:

- Reddening or tanning of the skin
- Occasional minor rectal bleeding
- Occasional minor bladder bleeding
- Chronic minor bowel or urinary symptoms as described above
- Erectile dysfunction

Rare but Serious:

- Urethral scar tissue
- Severe rectal or bladder bleeding
- Urinary or bowel incontinence
- Injuries to the rectum, bowel, or urinary system that can result in hospitalizations or major surgical procedures (example: colostomy - surgical creation of an artificial opening of the colon in the abdominal wall to bypass a damaged portion of the large bowel).

These potential, radiation-related side effects occur whether you receive radiotherapy with a regular treatment schedule or with a shortened treatment schedule (such as the treatment regimen used in this research study). It is possible that radiation side effects are more frequent or severe with a shortened treatment schedule than with a regular treatment schedule.

Radiation side effects occur whether you receive proton beam therapy or a regular radiotherapy. Because the way proton beam delivers a radiation dose, it is possible that you may experience less radiation side effects from proton beam therapy than from a regular radiotherapy. However, it is also possible that radiation side effects from proton beam therapy are as much as or even greater than regular radiotherapy.

Your doctor will discuss the risks of radiotherapy. You will also be told about hormone therapy (also called androgen deprivation therapy) which is part of standard medical care, and its side effects. In addition, you will be informed about the risks associated with any procedures or tests that are usually performed as part of standard medical care for the evaluation and treatment of your prostate cancer.

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

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

In addition, your doctor, the 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 your doctor and 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?

This study may not make your health better. However, the treatment offered in this research study can be effective and may reduce the chance of developing radiation-related side effects. At the same time, it may lower your healthcare costs because of the shorter treatment time. We hope that future patients will benefit from what we learn in this research study.

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:

- Proton beam therapy with a regular treatment schedule
- Standard conventional radiotherapy with a regular or shortened treatment schedule
- Surgical removal of the prostate and the pelvic nodes. You may still need radiotherapy even after surgery.
- Hormone therapy (androgen deprivation therapy) alone
- No treatment

Talk to your doctor or the Principal Investigator if you have any questions about any of these treatments or procedures.

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

There are no research related costs associated with the study.

All tests, procedures, radiotherapy, and hormone therapy described in this research study are part of standard medical care for your prostate cancer. Thus, you and/or your insurance will need to pay for all tests and procedures needed for your 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. You will have to pay for any costs not covered by your insurance.

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

You won't be paid for taking part in this study.

13. 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.

The confidentiality of your information will be safeguarded. For example, data collected for this study is kept on password-protected computers and networks, accessible only by the study 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.

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.
- 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?

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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.

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