MC1851 / 19-000708

A Randomized, Parallel Phase II Trial Of Hypofractionated Proton Therapy Or IMRT For Recurrent, Oligometastatic Prostate Cancer Involving Only Pelvic And/or Para-aortic Lymph Nodes Following Primary Localized Treatment

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MAYO CLINIC

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Not to be used after: **September 22, 2023**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC1851: A Randomized, Parallel Phase II Trial of Hypofractionated Proton Beam Therapy or IMRT for Recurrent, Oligometastatic Prostate Cancer involving Only Pelvic and/or Para-aortic Lymph Nodes Following Primary Localized Treatment

IRB#: 19-000708

Principal Investigator: Brian J. Davis, MD, PhD and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to find out if a shorter course of radiation is better for patients with recurrent prostate cancer. You have been asked to take to take part in this research because you were previously treated for prostate cancer and the cancer has returned.
What's Involved	Study participation involves being randomized to either Arm 1 (3 weeks of radiation) or Arm 2 (5 weeks of radiation). You are twice as likely to be assigned to the three week treatment course as to the five week treatment course.

	During your treatment, your doctor will evaluate your side effects weekly to see how you and your cancer are affected by the treatment you receive. At 3, 6, 12, 18, and 24 months after radiation, you will have a physical examination to evaluate any side effects from your treatment, PSA level check, and will be asked to complete questionnaires to assess your side effects and quality of life. At 6, 12, 24, 36, 48, and 60 months after radiation, you will have your testosterone level checked.
Key Information	Radiation side effects occur whether you receive proton beam therapy or a regular radiotherapy. Because of 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 could be the same or worse than regular radiotherapy. The risks associated with study participation are completely described later in this form, be sure to review them carefully.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

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 either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

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.

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Brian J. Davis, MD, PhD	**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, and https://www.mayo.edu/research/clinical-trials. These websites will not include information that can identify you. You can search this Website at any time.

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 were previously treated for prostate cancer and the cancer has returned.

The plan is to have about 84 people take part in this study at Mayo Clinic.

Why is this research study being done?

We are doing this research study to find out if a shorter course of radiation is as effective with fewer side effects for patients with recurrent prostate cancer.

Information you should know

Who is Funding the Study?
The Department of Radiation Oncology is funding this study.

Information Regarding Conflict of Interest:
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.

How long will you be in this research study?

Depending on the study arm you are selected for, your radiation treatment plan may be given for a duration of 3 weeks or 5 weeks. The study arms are discussed in detail, in the next section of this form. You will be in the study for a total of 5 years.

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

Before beginning any research activities you will be asked to sign this informed consent form.

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be 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 study doctor.

- History and physical exam
- PSA (prostate specific antigen) and serum total testosterone tests
- CBC and creatinine blood tests
- Symptom assessments
- CT scan of abdomen and pelvis, or MRI of pelvis
- Choline PET/CT or other advanced PET imaging

If the tests and procedures show that you are eligible to be in the study, you will be randomized to either **Arm 1** (3 weeks of radiation) or **Arm 2** (5 weeks of radiation). Randomization means you will be assigned by chance (like a coin toss) to the 3 week group or the 5 week group. You and the Principal Investigator cannot choose your study group. You are twice as likely to be assigned to the three week treatment course as to the five week treatment course.

During Treatment

Your doctor will evaluate your side effects weekly during radiation to see how you and your cancer are affected by the treatment you receive. These tests and procedures are part of standard clinical care.

After Treatment

At 3, 6, 12, 18, and 24 months after you have received your radiation treatment plan of 3 weeks or 5 weeks in duration, you will have a physical examination to evaluate any side effects from your treatment, PSA level, and will be asked to complete questionnaires to assess your side effects and quality of life. At 6, 12, 24, 36, 48, and 60 months after radiation, you will have your testosterone level checked. You may also have other tests and procedures if your doctor determines they are medically necessary.

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

Risks and side effects related to radiation to the pelvis and abdomen:
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
- Mild nausea

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 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 less frequent or severe with a shortened treatment schedule than with a regular treatment schedule, but it is also possible that the side effects are the same or worse than a regular treatment schedule.

Your doctor will discuss the risks of radiotherapy. You will also be told about hormone therapy (also called androgen suppression) 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.

Quality of Life Questionnaires:
During this study, we will ask you to complete four (4) questionnaires about your quality of life and treatment symptoms (good and bad). Each of the questionnaires will take about 10-15 minutes to complete.

- International Index of Erectile Function Questionnaire (IIEF)
- American Urological Association Symptom Index (AUA) – Urinary Symptoms
- PRO-CTCAE-GI/GU – Gastrointestinal symptoms experienced
- EPIC-26 – Urinary Symptoms

We hope that you will answer all of the questions, but you can skip any questions you don't want to answer or that make you feel uncomfortable.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

There may be other risks that are currently unknown. Other drugs may be given to make side effects less serious and less uncomfortable. Talk to the researcher and/or your healthcare provider about side effects and ask any other questions.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop.

In addition, 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.

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. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

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

This study may not make your health better and may not be as good as standard of care treatment. However, the side effects from this new treatment may be less than the side effects of standard treatment.

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:

- Receiving treatment or care for your cancer without being in the study
- Taking part in another study
- Getting no treatment

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

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

There are no tests or procedures being done just for this research study.

You and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

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

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

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

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information or samples collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.

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. Clinical and laboratory data will be stored in a secure electronic database. Patient identification numbers will be assigned to protect anonymity. The list of patient names and identification numbers will be kept locked by the Principal Investigator. If the results of the research are made public, information that identifies you will not be used.

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 (or "authorization") to Mayo Clinic.

Your health information may be collected from:

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

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- Researchers involved in this study at other institutions.
- The Mayo Clinic Institutional Review Board that oversees the research.
- 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.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media) information that identifies you will not be used.

In addition, individuals involved in study oversight and <u>not</u> employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

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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 Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic 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.

You can cancel your permission for Mayo Clinic 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
201 Building 4-60
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.

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Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

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