MC1623 / 16-008343

Phase II Trial of Standard Chemotherapy (Carboplatin & Paclitaxel) Various Proton Beam Therapy (PBT) Doses in Order to Determine the Optimal Dose of PBT for Unresectable Stage 2/3 Non-Small Cell Lung Cancer

NCT03132532

Document Date: 09/01/2023

MAYO CLINIC

Name and Clinic Number

Approval Date: **September 1, 2023**
Not to be used after: **December 20, 2023**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC1623: Phase II Trial of Standard platinum doublet chemotherapy +various proton beam therapy (PBT) doses in order to determine the optimal dose of PBT for unresectable stage 2/3 Non-Small Cell Lung Cancer

IRB#: 16-008343

Principal Investigator: Terence T. Sio, M.D., M.S. 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.

MAYO CLINIC

Name and Clinic Number

Approval Date: **September 1, 2023**
Not to be used after: **December 20, 2023**

CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Terence T. Sio, M.D., M.S. **Co- Principal Investigator:** Yolanda I. Garces M.D.	**Phone:** (480) 342-1262 **Phone:** (507) 284-8227 **Address:** Mayo Clinic 5777 E. Mayo Boulevard Phoenix, AZ 85054 Mayo Clinic 200 First St. 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 Participant Advocate **(The RPA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@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 ▪ Withdrawing from the research study
Patient Account Services	**Toll Free:** (844) 217-9591	▪ Billing or insurance related to this research study

Approval Date: **September 1, 2023**
Not to be used after: **December 20, 2023**

Other Information:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

A description of this research study will also be available on Mayo Clinic Clinical Trials Web site http://www.mayo.edu/research/clinical-trials?_ga=1.25502715.752922363.1409934783. This Web site 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 participate in this study because you have been diagnosed with Non-Small Cell Lung Cancer (NSCLC) and your physician feels that proton radiotherapy would be the best option for you along with standard of care chemotherapy options.

The plan is to have about 50 people take part in this study at Mayo Clinic.

2. Why is this research study being done?

This research is being done to study which dose of proton radiotherapy is best for this particular type of cancer. Each of the doses available in this study has been given to patients with NSCLC in the setting of photon radiotherapy.

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 this research study for about five years. The duration of radiation therapy and chemotherapy will be about 6-7½ weeks. Follow-up visits will be scheduled every 3 months for 3 years and then every 6 months for the remaining 2 years. These visits coincide with when your care teams would like to see you back standardly.

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

Before you begin the study:
If you agree to be in this study, you will need to have the following exams, tests, and procedures. These may be part of regular cancer care and may be done even if you do not join this study.

- History and physical exam
- Serum pregnancy test (if you are of child-bearing potential)
- Pulmonary function tests
- CT of the chest
- PET/CT
- MRI or CT of the head
- Questionnaire
- Blood sample to check certain blood components

If all the required tests and exams show that you can be in the study and if you choose to take part, you will be "randomized" to one of the study arms described below. Randomization means that you are put into a study arm by chance (like a coin toss).

Arm A: standard of care chemotherapy and proton beam radiotherapy (60 Gy in 2 Gy daily fractions) 30 weekdays of treatment.

Arm C: standard of care chemotherapy and proton beam radiotherapy (72 Gy in 2 Gy daily fractions) 36 weekdays of treatment.

Further therapy, if any after radiation, will be discussed by the treating Physician.

During radiotherapy:

- Weekly exams
- Weekly blood sample to check certain blood components
- Assessment of symptoms

Follow-up after radiotherapy: You will have follow-up visits for 5 years after radiotherapy: Every 3 months (+/-1 month) for 3 years after radiotherapy and then every 6 months (+/-3 months) for an additional 2 years after radiotherapy.

- History and physical exam
- Assessment of symptoms
- Pulmonary function tests (this will be completed at 1 year post radiotherapy)
- CT Chest (when indicated by your doctor)
- Questionnaire
- Blood sample to check certain blood components (in the first 3 years when indicated by your doctor)

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

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

- Reddening or peeling of the skin during treatment and for several weeks following treatment
- Cough due to lung inflammation
- Difficulty breathing due to lung inflammation
- Tanning of the skin or lightening of the skin lasting months and may be permanent
- Mild thickening or firming of the soft tissue and skin on touch
- Tiredness and weakness during treatment and for several weeks following treatment
- Mild to moderate pain at the site of radiation treatment that may require pain relievers
- Esophageal irritation which is mild to moderate and causes painful swallowing

Less likely *(these side effects occur in **3-9%** of patients):*

- Soreness or tightness in muscles of the chest wall
- Severe pain at the site of radiation treatment requiring prescription pain relievers
- Prominent thickening or firming of the soft tissues
- Esophageal irritation which causes severe pain and requires prescription pain relievers
- Nausea

Rare but serious *(these side effects occur in less than **3%** of patients):*

- Severe difficulty breathing which could require oxygen due to inflammation of the lung or in rare instances may result in death
- Inflammation of the heart
- Rib fracture
- Slight increase in risk of developing heart disease
- Risk of developing another cancer due to radiation therapy (risk of about ≤1%)

Standard of Care Risks:
Your doctor will discuss the risks of chemotherapy, blood draw, pulmonary function test, CT, PET/CT, and MRI, as these tests and procedures are part of your standard clinical care.

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. Combined modality therapy (standard radiation and chemotherapy) can cause toxicity severe enough to result in death in 1-4% of patients treated and same is possible when proton beam therapy is combined with chemotherapy. However, this (combination of radiation therapy and chemotherapy) treatment generally prolongs life and cures some patients with unresectable stage 2-3 non-small cell lung cancer with 5-year survival ranging from 15 to 30% of those treated.

Your doctor will discuss the risks of radiotherapy. 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 cancer.

Reproductive risks:
You should not become pregnant while undergoing radiotherapy on this study because the radiation therapy in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. If you are a woman able to have children and have not been surgically sterilized (tubal ligation or hysterectomy), you should have a pregnancy testing 7 days prior to registration and agree to use acceptable birth control (see list below). A pregnancy test will be done as part of your normal clinical care. If you are pregnant, you will not be allowed to participate. You should not become pregnant while on this study, but if you should become pregnant while you are on this study, you must tell your study doctor immediately. Ask about counseling and more information about preventing pregnancy.

If you are sexually active and able to become pregnant while undergoing radiotherapy on this study, you must agree to use one of the birth control methods listed below:

- Approved hormonal contraceptives, such as birth control pills, patches, injections, vaginal ring, or implants
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- An intrauterine device (IUD)
- Abstinence (no sex)

7. 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 and you will be advised whether any additional tests may need to be done for your safety.

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.

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. While researchers hope that this method of delivering radiation therapy with proton therapy will be safer and more effective against cancer compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help researchers determine the best dose of fractionated proton therapy to use within the range of doses investigated. This information could help future cancer patients.

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:

- Getting radiation therapy treatment for your cancer without being in a 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.

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 chemotherapy described in this research study are part of standard medical care for your lung 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 (or "authorization") to Mayo Clinic.

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.
- 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.

In addition, individuals involved in study oversight and not 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.

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.

Approval Date: **September 1, 2023**
Not to be used after: **December 20, 2023**

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 Participant Advocate at: researchparticipantadvocate@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.

Approval Date: **September 1, 2023**
Not to be used after: **December 20, 2023**

ENROLLMENT AND PERMISSION SIGNATURES:

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

	/ /	: AM/PM
Printed Name	Date	Time

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.

	/ /	: AM/PM
Printed Name	Date	Time

Signature