MC1732 / 17-004130

A Pilot/Phase II Trial of Hypofractionated Radiotherapy to the Whole Breast Alone before Breast Conserving Surgery

NCT03624478

Document Date: 07/02/2020

MAYO CLINIC

Name and Clinic Number

Approval Date: **July 2, 2020**
Not to be used after: **July 1, 2021**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC1732, A pilot/phase II trial of hypofractionated radiotherapy to the whole breast alone before breast conserving surgery

IRB#: 17-004130

Principal Investigator: Carlos Vargas, M.D. 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 Laura A. Vallow, MD Florida	**Phone:** (480) 342-4800 **Institution Name and Address:** Mayo Clinic Arizona 5777 E. Mayo Blvd. Phoenix, AZ 85054 **Phone:** (904) 953-2000 **Institution Name and Address:** Mayo Clinic Florida 4500 San Pablo Rd. S, Jacksonville, FL 32224	▪ 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	**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. 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.

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 breast cancer, plan to have treatment of whole breast radiotherapy and breast surgery, but have not yet had breast cancer surgery. The plan is to have about 25 people take part in this study at Mayo Clinic.

2. Why is this research study being done?

Very little information exists about changes that occur to breast cancer tissue and cancer DNA (Deoxyribonucleic acid) during x-ray or proton radiotherapy. DNA is the genetic information you inherited from your parents (also known as genetic testing).

The purpose of this study is to conduct x-ray or proton radiotherapy before breast cancer surgery and examine the changes to the cancer tissue removed during surgery.
Proton therapy is a type of radiation therapy — a treatment that uses high-energy beams to treat tumors. Radiation therapy using x-rays has long been used to treat cancers and noncancerous (benign) tumors. Proton therapy is recognized as a standard option for the delivery of radiotherapy for breast cancer. Radiation is part of the treatment for breast cancer.

3. Information you should know

Who is Funding the Study?

Mayo Clinic Benefactor funds are supporting this study.

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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.

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

You will be in this study for up to 5 years. This timeline includes study follow-up.

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

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

Screening
The Screening Visit will take about 2-3 hours. During this 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:

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Draw a blood sample
- Test your blood for pregnancy if you are a female able to become pregnant
- Test your blood for DNA as a control for tissue analysis (approximately 4 tablespoons)
- Take a sample of breast tissue to confirm breast cancer diagnosis and analyze DNA
- Give you some questionnaires to fill out about your general health and well-being, quality of life, emotional health and mood. The questionnaires will take about 1 hour to complete.
- Take digital photographs (three positions)

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Radiation Therapy
You will have approximately 5 days (not including holidays or weekends) of radiotherapy. Each visit will take about one hour. Radiation therapy is part of your standard clinical care.

Post-Radiation Therapy
This visit will take about 2 hours. At this visit we will:

- Give you some questionnaires to fill out about your general health and well-being, quality of life, emotional health and mood. The questionnaires will take about 1 hour to complete
- Ask you about side effects or health problems since your last visit
- Take digital photographs (three positions)

Surgery
At this visit you will:

- Have breast cancer surgery (as part of your standard of care)
- Have a sample taken from the cancer tissue removed during surgery to analyze DNA
- Draw a blood sample (approximately 4 tablespoons)
- Ask you about side effects or health problems since your last visit

Follow-Up
Follow-up visits will occur at the following time points:

- Year 1 at 12 weeks, 6 months, and 12 months after radiotherapy
- Year 2 and 3 at 24 months and 36 months after radiotherapy
- 5 years after radiotherapy

Each visit will take about 1-2 hours. At these visits we will:

- Give you some questionnaires to fill out about your general health and well-being, quality of life, emotional health and mood. The questionnaires will take about 1 hour to complete
- Take digital photographs (three positions)
- Ask you about side effects or health problems since your last visit

Disease Site Recurrence
If you experience disease site recurrence, we will ask you to come in for one additional visit which will last 1-2 hours. At this visit we will:

- Give you some questionnaires to fill out about your general health and well-being, quality of life, emotional health and mood. The questionnaires will take about 1 hour to complete
- Ask you about side effects or health problems since your last visit
- Conduct a positron emission tomography (PET) scan (only if recommended by study physician; optional). A PET scan is an imaging test that allows your doctor to check for diseases in your body.

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

Radiation Risks

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

- Reddening of the skin during treatment and for several weeks following treatment
- Tanning of the skin lasting months and may be permanent
- Change in the skin or how the reconstructed breast looks
- Mild thickening or firming of the soft tissue and skin on touch

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 or breast on touch
- Swelling of soft tissues or breast
- Peeling of the skin in the area treated with radiation

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

- Cough
- Difficulty breathing
- Inflammation of the heart muscle
- Rib fracture
- Slight increase in risk of developing heart disease
- Risk of developing another cancer due to radiation therapy

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. It is important you understand that you must use birth control while on this study and for 1 year after. 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)

Genetic Testing – May be notified of test results

This study involves testing your DNA, which is the genetic information you inherited from your parents (also known as genetic testing). If a researcher finds that results from the genetic testing performed on your samples may be useful for your health care, you may be contacted and given the choice to learn the test results. At this time, you will be given general information on the potential risks, benefits, and costs of choosing to learn the test results. The risks of learning genetic test results may include emotional upset, insurance or job discrimination, and/or changes in family relationships because test results may affect other blood relatives. No genetic test results will be put into your medical record unless you choose to learn the results of the testing. Sometimes results should be released only through a genetic counselor who can help explain the possible risks and benefits of learning this information, as well as what these results could mean for you and your family.

Genetic Information Nondiscrimination Act (GINA)

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law.

Be aware that this new Federal law doesn't protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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

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

Standard of Care Risks
Your doctor will discuss the risks of proton radiotherapy, physical exams, surgery, digital photographs, biopsies, and optional PET imaging as these tests and procedures are part of your standard clinical care.

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.

If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit. The final study visit will take 3-4 hours. At this visit, we will perform the assessments identified under "Disease Site Recurrence" in section 5.

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?

This study may not make your health better. Others with breast cancer may benefit in the future 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:

- Getting radiation therapy, surgery, or other 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?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Blood draws for research
- Blood and tissue DNA analysis

However, 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. These tests and procedures are:

- Physical Exams
- Pregnancy test (if applicable)
- All costs related to surgery
- All costs related to Radiation Therapy
- Optional PET scan (if applicable)

You will also be responsible for any co-payments and deductibles.

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

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

13. What will happen to your samples?

We would like to keep your sample for future research. You can still take part in this current study even if you don't want your sample used for future research. If you agree to give your sample, it will be the property of Mayo Clinic.

Other researchers at Mayo Clinic who aren't involved with this study may ask to use your sample for future research. Researchers at other institutions may also ask for a part of your sample for future studies. If you approve release of your sample by checking 'yes' below, Mayo may send the sample(s) and some information about you to researchers who request them, but Mayo will <u>not</u> send your name, address, phone number, social security number, or any other

identifying information with the sample. Your sample will be sent to researchers in a coded format, which protects your identity.

Some future studies may examine your DNA, which is the genetic information you inherited from your parents (genetic testing). The Principal Investigator may contact you if there are findings which may be useful for your health care. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

Please read the following statements and mark your choices:

1. I permit my sample to be stored and used in future research of *breast cancer* at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my sample to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat any other health problems:

☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit Mayo Clinic to give my sample and related information to researchers at other institutions:

☐ Yes ☐ No Please initial here: _____Date: _____

There is a very small chance that some commercial value may result from the use of your donated sample. If that happens, you won't be offered a share in any profits.

You may request to have your sample destroyed by writing to the Principal Investigator. The address is found in the "Contact Information" section of this consent form.

Because we cannot predict how your sample will be used in the future, we cannot promise that samples can be retrieved and destroyed.

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 study. 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.

Your health information may be collected from:

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

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

- Do the research.
- Report the results.
- See if the research was done 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.
- 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.

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 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.

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
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.

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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 forever, unless you cancel it.

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