Official Title:	Accelerated, Hypofractionated Post-Mastectomy Radiation Therapy in Women with Breast Cancer: A Phase II Trial
NCT number:	NCT01417286
Document Type:	Study Consent - Main
Date of the Document:	01/10/2014

[redacted]

Consent for Participation in a Research Project
Rutgers Cancer Institute of New Jersey

Title of Study: Safety and Feasibility of Accelerated, Hypofractionated Post-Mastectomy Radiotherapy in Women with Breast Cancer: A Phase II Trial

Principal Investigator: [redacted]

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

Why have I been asked to take part in this research study?

You are being asked to take part in this study because you have breast cancer and have had or will have surgery to remove the cancer, and as part of your treatment, you will need radiation therapy following surgery to help lower the chance of the cancer returning.

Who is conducting the study?

[redacted]

Why is this research study being done?

Studies have shown that giving radiation therapy after mastectomy reduces the chance of the cancer coming back on the chest wall or the draining lymph nodes. Radiation delivered after a mastectomy is referred to as post-mastectomy radiation therapy. The standard (usual) course of post-mastectomy radiation therapy (PMRT) is given 5 days a week for 5 to 7 weeks. When radiation therapy is delivered after mastectomy, it is directed at the chest wall and the draining lymph nodes.

In this study, women who are to receive radiation after mastectomy will receive accelerated radiation therapy to the chest wall and draining lymph nodes in 11 treatments. This is referred to as accelerated post-mastectomy radiation therapy (A-PMRT). The term "accelerated" means that a higher radiation dose per treatment will be delivered over a shorter period of time (compared to the standard). Prior studies suggest that the accelerated radiation scheme used in this study may be

EXPIRES
JAN 09 2015
[redacted]

APPROVED
JAN 10 2014
[redacted]

NCI CCC
A Comprehensive Cancer Center Designated by the National Cancer Institute

comparable to the standard or conventional schedule of radiation therapy. In other words, the evidence supports that accelerated treatments may work at least as well as the longer, standard treatments, but will be much more convenient for patients than the standard treatments. This is the reason we are doing this research – to find out if shorter, more accelerated radiation treatments will have the same success of preventing breast cancer tumors from returning.

How many people will take part in the study?
About 44 women will take part in the study at [redacted]

Who may or may not take part in this study?

To be eligible and be included to take part in this study:

- Diagnostic and laboratory tests and procedures must show that the type of breast cancer you have qualifies and is within Stage I-IIIc.
- You must have had or will have surgery (mastectomy) to remove the qualifying cancer, and as part of your treatment, you will need radiation therapy to your breast to help prevent the cancer from returning.
- Your cancer must not have spread to other parts of your body.
- You must be18 years or older and able to spend the majority of the day out of bed.
- There are time limitations from date of surgery to enrollment and treatment in this study. Chemotherapy is allowed, but again, there are scheduling/timing limitations. Please discuss these time limitations with your oncologist to see if you qualify for this study.
- You must sign the consent form.

There are factors that may exclude you from participation, which may be identified during the screening process:

- If you have had prior radiation treatment to the chest area.
- If you had previous breast cancer.
- If you have collagen vascular disease, specifically systemic lupus, erythematosis, scleroderma, or dermatomyositis.
- Women who are pregnant or breast feeding, or if you are able to get pregnant and you do not use effective birth control.
- If your breast disease is not invasive (in other words non-invasive tumors such as DCIS and LCIS are not allowed)

What will happen if I take part in this research study?

Before you begin the study: Before you are on the study, you will have your mastectomy. In order to register for the study, the following exams, tests, and procedures must show that you are eligible (qualify to be in the study). These exams, tests, and procedures are part of regular cancer care and

may be done even if you do not join this study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor. If you need chemotherapy and your medical oncologist sequences that before your radiation therapy, you must wait until at least 3 weeks after your chemotherapy to begin your radiation therapy on this study. Your radiation treatment planning, including obtaining a CT scan to help aim the radiation, can begin 2 weeks after your chemotherapy ends. You may receive chemotherapy before your mastectomy and still be eligible for the study.

- history and physical exam
- chest x-ray or chest CT scan
- breast exam
- CT scan of the breast that had the cancer to help plan the radiation therapy
- blood tests (including a pregnancy test for women of childbearing potential).

During the study: If the exams, tests, and procedures show that you can be in the study, and you choose to take part, you must sign the informed consent form. At this time you are registered on the study and you will then undergo radiation treatment planning (CT Simulation).

You will receive 11 radiation treatments that are directed at the chest wall and possibly (based on your oncologists discretion) at the draining lymph nodes under the arm, under the breast bone, and around the collar bone. Sometimes doctors treat the area around the mastectomy scar with a higher dose of radiation, referred to as a "boost" or a "scar boost" and your physician may choose to do this.

FOR ALL PATIENTS: Radiation does not stay in your body between treatments or after the final treatment.

Radiation Treatment Schedules

If you do not need chemotherapy or if your chemotherapy was delivered before the mastectomy

- You must wait at least 2 weeks after your mastectomy to register for the study and for radiation treatment planning (CT Simulation).
- Three weeks from your mastectomy is the earliest that you can start your radiation treatments.
- A-PMRT treatments are once daily for 11 consecutive weekdays. Each daily treatment of A-PMRT lasts around 10 – 15 minutes.
- Your treating doctor may choose to add an optional "boost" treatment to the scar area. A maximum of 4 additional treatments may be given on consecutive weekdays. Each treatment will last 10-15 minutes.

If you need chemotherapy: Your medical oncologist will sequence your chemotherapy either before or after radiation treatments. The most important rule for this category is that you must wait at least 3 weeks between chemotherapy and radiation therapy (or radiation therapy and chemotherapy).

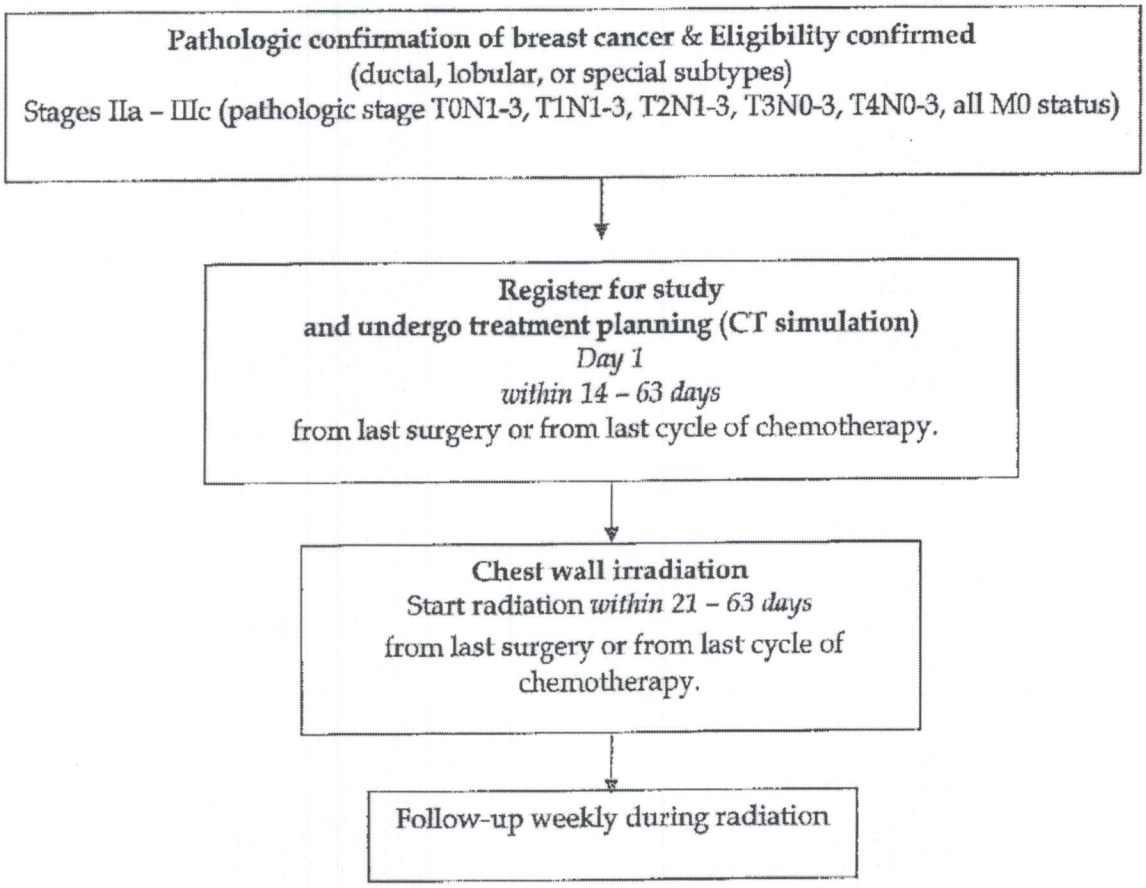
If your doctor prescribes chemotherapy first

- You will complete your chemotherapy. At this point you are not on the study yet.
- You must wait at least 2 weeks after your chemotherapy treatments before you register for the study and start radiation treatment planning (CT Simulation).
- Radiation treatments begin within 3 – 9 weeks from the end of chemotherapy.
- A-PMRT treatments are once daily for 11 consecutive weekdays. Each daily treatment of A-PMRT lasts around 10 – 15 minutes.
- Your treating doctor may choose to add an optional "boost" treatment to the scar area. A maximum of 4 additional treatments may be given on consecutive weekdays. Each treatment will last 10-15 minutes.

If your doctor prescribes radiation therapy first

- You must wait at least 2 weeks after your mastectomy to register for the study and for radiation treatment planning (CT Simulation).
- You must start radiation within 3-9 weeks of your mastectomy.
- A-PMRT treatments are once daily for 11 consecutive weekdays. Each daily treatment of A-PMRT lasts around 10 – 15 minutes.
- Your treating doctor may choose to add an optional "boost" treatment to the scar area. A maximum of 4 additional treatments may be given on consecutive weekdays. Each treatment will last 10-15 minutes.
- You must wait at least 3 weeks after finishing radiation treatments before chemotherapy can begin.

Study Schema – Accelerated postmastectomy radiation therapy



If chemotherapy is indicated and is delivered after RT, it must start ≥ 21 days after completion of RT.

RT time = 11 weekdays (once/day) chest wall irradiation = 11 RT days

Total Elapsed Time = 11 total weekday RT = **15 elapsed days (mastectomy scar boost optional up to 4 fractions, 4 weekdays=19 elapsed days)**

How long will I be in the study?

You will be on study from the time consent is signed until the end of radiation treatments. This total time should be less than 8 weeks, with the radiation lasting less than 30 days. At the end of radiation therapy, you will continue seeing your surgeon, medical oncologist or radiation oncologist as noted below, which is part of the normal follow-up for a cancer patient. Patients will be seen in follow-up weekly during treatment, at the end of radiation, then 2-8 weeks after radiation treatments, then every 3-6 months for 3 years, then every 6-12 months out to 5 years.

During the first two years after finishing the study, you will have the following tests and procedures performed:

- *A brief history and physical exam* at the end of radiation therapy, then at week 2-8 after radiation therapy, then every 3-6 months for the first 3 years.

During 3-5 years after finishing the study, you will have the following tests and procedures performed:

- *A brief history and physical exam and an examination of your chest wall* will be performed every 6-12 months after finishing radiation therapy, or after finishing radiation therapy and chemotherapy, if received.

After the 5th year after finishing the study, a brief history and physical exam will be performed at a schedule decided upon by your treating doctors.

Can I stop being in the study?

Yes, you can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the study treatment can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

If you change your mind, you must revoke your approval in a written request to Dr. Atif Khan at the address on the first page of this consent. Beginning on the date you revoke your approval, no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your approval.

You can choose to withdraw in one of two ways. In the first, you can stop your study treatment but still allow the study doctor to follow your care. In the second, you can stop your study treatment and not have any further contact with the study staff.

Can anyone else stop me from being in the study?

The study doctor may stop you from taking part in this study at any time if he or she believes it is in the best interest for your health, if you do not follow the study rules, or if the study is stopped by CINJ.

What side effects or risks can I expect from being in the study?

You may have side effects while on this study. Most of these are listed here, but there may be other side effects that we cannot predict. Side effects will vary from person to person. Everyone taking part in the study will be carefully watched for any side effects. However, doctors do not know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medications to help lessen some of the side effects. Many side effects go away soon after your radiation therapy. In some cases, side effects may be very serious, long-lasting, or may never go away.

You should talk with your study doctor about any side effects that you may have while taking part in the study.

Risks and side effects related to a course of accelerated post-mastectomy radiation therapy (A-PMRT) (while these risks apply to all patients undergoing chest wall irradiation, they may occur more (or less) frequently with the accelerated course of radiation)

Likely effects

These side effects occur in patients receiving chest wall irradiation:

- reddening of the skin during treatment and for several weeks following treatment
- tanning of the skin lasting months and may be permanent
- tiredness and weakness during treatment and for several weeks following treatment
- muscles in chest wall under treated breast may feel tight or sore

Less likely effects

These side effects occur in patients receiving chest wall irradiation:

- peeling of the skin in the area treated with radiation
- pain at the site of radiation treatment
- painless dilated blood vessels under skin called telangiectasia

Rare but serious effects

These side effects are **rare but serious**, occurring in patients receiving whole breast radiation therapy or chest wall irradiation:

- cough
- difficulty breathing
- irritation of the sac surrounding the heart
- inflammation of the heart muscle
- rib fracture
- another cancer due to radiation therapy
- injury to the nerves carrying sensation and movement to the upper extremity (arm)

IRB# 0220100204
Version Date: 12/12/13

Risk related to fertility and pregnancy

If you are pregnant, you cannot take part in this study. Radiation therapy, even when delivered at a site away from the pregnant abdomen/pelvis, can result in radiation dose to the unborn baby that can be harmful to the baby. Effects of radiation on an unborn baby can include organ malformation and mental retardation. Because of this, you should not become pregnant if you decide to take part in this study.

If you are currently breast feeding a child and agree to participate in this study, you must stop breast feeding before receiving the first dose of radiation. You must agree to discontinue breast feeding for the entire time you are participating in the study to prevent any potential health risk or injury to the child. Although the breast milk will never transmit radiation to your baby, the texture and quality of the milk may change due to changes in the breast from the radiation. Ask your doctor for more information

If you are capable of becoming pregnant, a pregnancy test (using a urine and/or blood sample) will be done and the results must be negative before you are permitted to enroll in this study. A repeat pregnancy test must be done if you miss any periods or your menstrual cycle becomes irregular.

If you have not gone through menopause, we can provide you with more information about preventing pregnancy. .

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

Are there benefits to taking part in this study?

Taking part in this study may or may not make your health better. While doctors hope that A-PMRT will be at least as effective in preventing breast cancer recurrences as standard PMRT, there is no proof of this yet. One benefit of this treatment is the reduced overall treatment time. We do know that the information from this study will help doctors learn more about accelerated PMRT as a treatment for breast cancer. This information could help future cancer patients.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Receiving standard PMRT over 6 weeks without being in this study
- Getting treatment or care for your cancer without being in this study
- Taking part in another study
- Getting no radiation treatment

Please talk with your doctor about your choices before you decide if you will take part in this study.

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Information for this trial will be kept on a secure password-protected computer that will allow access to only the study personnel. Your

personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, for quality assurance, and data analysis include:

- [redacted]
- [redacted]
- [redacted]

see that it is being done safely and correctly.

What are the costs of taking part in this study?

You and/or your health plan insurance company will need to pay for all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

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

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, [redacted] if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him or [redacted]

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be responsible for the costs of this treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

EXPIRES

APPROVED

JAN 09 2015

[redacted]

JAN 10 2014

[redacted]

The Data Monitoring Committee (DMC), an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. You may be asked to sign another consent form in response to new information.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any question or concerns you may have about this study. [redacted]

[redacted]

- You may call the National Cancer Institute's (NCI's) Cancer Information Service at: 1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web Site at http://cancer.gov
For the NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials
For the NCI's general information about cancer, go to: http://cancer.gov/cancerinfo

You will receive a copy of this form. If you want more information about this study, ask your study doctor.

Signatures

I have been given a copy of all ___ pages of this form. I have read the consent form or it has been read to me. This information was explained to me and my questions were answered.

I agree to take part in this research study.

Date	Patient's signature
Date	Signature of person conducting the informed consent discussion

APPROVED
JAN 10 2014

EXPIRES
JAN 09 2015

[redacted]

[redacted]