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Patient Engagement to Get The Question Right

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C. Daniel Mullins

- Overview of RadComp
- Patient Input for RadComp

PRAGMATIC PHASE III RANDOMIZED TRIAL OF PROTON VS. PHOTON THERAPY FOR PATIENTS WITH NON-METASTATIC BREAST CANCER RECEIVING COMPREHENSIVE NODAL RADIATION: A RADIOTHERAPY COMPARATIVE EFFECTIVENESS (RADCOMP) CONSORTIUM TRIAL

Radcomp
PATIENT POWERED
A study at the heart of breast cancer treatment

PATIENTS

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PCORI Disclaimer

The views presented in this presentation are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.

RADCOMP Trial: Study Overview

A pragmatic clinical trial in which patients with non-metastatic breast cancer will be randomized to either **PR**oton or **PH**oton therapy and followed longitudinally for cardiovascular morbidity and mortality, cancer control outcomes and health-related quality of life (**HRQOL**)

Unifying Hypothesis

*We hypothesize that **PR**oton therapy, as part of multi-modality curative treatment for locally-advanced breast cancer, reduces major cardiovascular events (MCE), is non-inferior in cancer control, and improves HRQOL compared to **PH**oton therapy, the current standard treatment.*

PRoton versus PHoton Therapy

Treatment	Potential Benefits	Potential Risks
PHOTON THERAPY	• Doctors can aim and shape radiation beams, so you get the right amount of radiation • Widely used to treat breast cancer for many years • Short- and long-term risks and benefits are well-documented	• Passes through healthy tissues on its way to AND beyond the tumor target • Healthy tissue, like the heart, can be damaged by the radiation, possibly causing side effects
PROTON THERAPY	• Doctors can aim and shape radiation beams, so you get the right amount of radiation • Passes through healthy tissues as it enters the body (like PHOTON THERAPY) but stops after it has reached the target areas (unlike PHOTON THERAPY); this may cause less radiation damage to healthy tissue	• More sensitive to denser organs and to organs like the lungs, heart, and chest wall that may move during treatment; this may reduce the accuracy of the radiation beam • Healthy tissue, like the heart, can be damaged by the radiation, possibly causing side effects • Short- and long-term risks and benefits are not as well-documented as PHOTON THERAPY

Role of Stakeholder Advisory Committee

- Active participation in an all-day meeting (in-person in first and last years of project and via video/teleconference in years 2, 3, and 4)
- Participation in 3-4 Stakeholder Advisory Committee conference calls per year
- Reviewing materials prior to meetings and calls
- Providing advice and guidance
- Participation ≈ 4 days per year

C. Daniel Mullins

- Overview of RadComp
- Patient Input for RadComp

Minnie Reddy

- My Journey into
  - CER/PCOR
  - The PATIENTS Program
  - The NCI meeting for a PCORI project

- The Importance of Framing the Question

  “When are we going to talk about healing?”

RadComp:
How patient input has transformed the study

Primary endpoint

During trial design phase, patients expressed that their primary concern was major heart problems (such as heart attacks) after cancer treatment for locally advanced breast cancer.

This endpoint became the primary endpoint.

Primary endpoint (2)

"Of course I would want to know if proton therapy will improve the skin burn or my tiredness after radiation. But, I would be more motivated to participate in a big study if I knew we would learn whether proton therapy could avoid causing problems with my heart. That would help me weigh whether the long-term benefits of radiation outweigh the long-term side effects."

- Breast Cancer Survivor, Rochester, MN

Trial design

Patients wanted the study to make sure the new therapy (PRoton therapy) “cured” breast cancer just like usual treatment (PHoton therapy). However, investigators felt there would be no difference in efficacy between the two treatments studied. Nonetheless, investigators altered the study design to scientifically test whether the treatments were not inferior to each other in cancer control.

Brief Handout for Patients

RadComp
PATIENT POWERED

A Study Comparing Two Types of Radiation Therapy for Breast Cancer

What is this study about?

In this study, we are looking at two different radiation treatments for your breast cancer: **PH**oton Therapy (pronouced "*fo-tahn*") and **PR**oton Therapy (pronouced "*pro-tahn*"). Both work and neither is experimental.

What happens if you take part in the study?

You will be randomly assigned to receive either **PH**oton Therapy or **PR**oton Therapy and then you will have daily radiation treatments according to usual medical practice for 5 to 7 weeks.

What do we hope to learn?

We want to learn if one type of radiation (**PH**oton Therapy or **PR**oton Therapy) is better at helping you live longer or have a better quality of life.

▶ *To learn more about this study, talk with your doctor or visit us at* **www.radcomp.org.**

QUESTIONS AND DISCUSSION