Alliance A221505: RT CHARM: Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation with Breast Reconstruction

Matthew M. Poppe, MD

Huntsman Cancer Hospital, University of Utah

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Rationale

In the last 5-10 years, there has been a significant shift in the radiation of women with intact breast cancer to shorter, more cost effective and convenient treatment courses. As the outcomes with traditional post mastectomy are already considered safe and effective, this trial is designed as a non-inferiority trial to ensure that a shorter time course of radiation is as safe as the current standard of care. There are two pressing and currently outstanding questions related to hypofractionation that require resolution in a phase III setting

1. What is the rate of radiation related complications in reconstructed chest walls treated with shortened course radiotherapy? and
2. Is hypofractionation safe when treating regional nodal volumes (where the brachial plexus is located)?

These two questions have been contentious and their uncertainty will directly affect patient care for years to come, unless a well-designed study can define the unknowns. In this study, both of these questions will be tested and resolved as primary and secondary endpoints. This trial design also will collect much needed prospective data regarding the true complication rates for post mastectomy radiation therapy (PMRT) with breast reconstruction, given the multitude of options for breast reconstruction timing and techniques. This trial design also collects much needed prospective data regarding the true complication rates for PMRT with breast reconstruction, given the multitude of options for breast reconstruction timing and techniques.

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Objective

Primary

- **Non-inferior reconstruction complication rate at 24 months post radiation with hypofractionation.**
- Complications will include any re-operation or hospitalization considered as non-routine, as well any baker 3 or 4 contracture

Secondary

- Acute and late radiation complications, based on CTCAE 4.0 toxicity.
- Local and local regional recurrence rate.
- Photographic cosmesis 24 months after radiation.
- Lymphedema at 24 months after radiation.
- Patient satisfaction and well-being at 24 months after radiation (Breast Q)
- Compare reconstruction complication rates based on reconstruction method and timing of reconstruction.
- Cost and healthcare utilization based on hypofractionation and reconstruction technique

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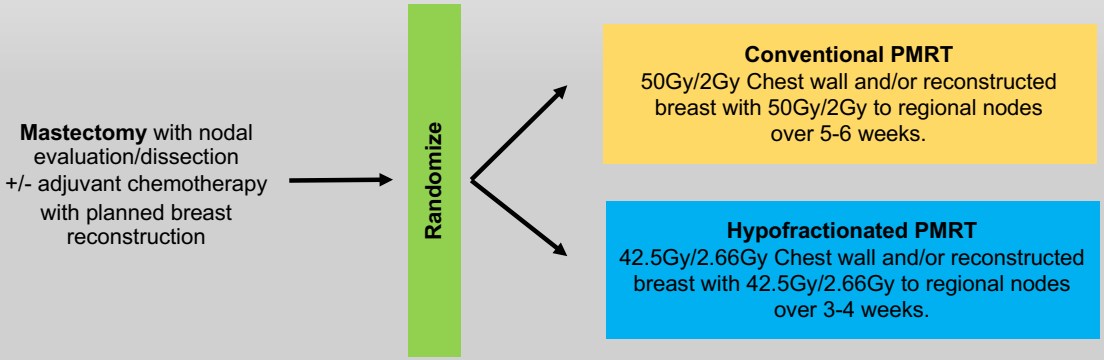
NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

Study Schema



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Regional Nodes will include axilla (Level I, II, III), supraclavicular fossa and internal mammary nodes. If an axillary dissection has been performed. RT will only be directed to the un-dissected axilla.

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Treatment Plan

Surgery	Reconstruction	Radiation Therapy	Chemotherapy
• Total, simple, skin sparing, nipple sparing or modified radical mastectomy. • Margins should be negative, defined as no tumor on ink. • Focally positive deep margin will be acceptable if the deep margin is the pectoralis fascia and the pectoralis fascia was noted as removed in the operative description or pathology report. • Lymph nodes must be evaluated by sentinel node biopsy or axillary dissection. • If contralateral breast surgery, no invasive disease in contra-lateral breast (DCIS okay)	• Reconstruction of the breast may occur before of after radiation. • Tissue expander may be placed before or after radiation and maybe inflated or deflated for radiation • Plastic surgeon may use any combination of allograft, implant or tissue flap for reconstruction. • Reconstruction intent must be stated at the time of registration (timing and implant vs. autologous) • Intent to complete reconstruction within 8 months of radiation (approximately 1 year from mastectomy)	• Similar volume based planning to A11202 and NSABP B51. • RT must start within 84 days of mastectomy or adjuvant chemo (whichever is later) • 2.66Gy x 16 daily to reconstructed CW and regional nodes (IM coverage required). No boost allowed. • RT QA through IROC Rhode Island • Data submission within 3 days of starting RT • IMRT QA grand-fathered if completed for A11202/B51 • Proton RT not allowed at this time	• Per standard of care • Neoadjuvant or adjuvant allowed • May be delivered before or after PMRT • No concurrent chemotherapy with RT other than anti-Her2 or other biological therapy • Minimum 21 days between chemotherapy and RT • Adjuvant hormonal therapy per treating physician • If Neoadjuvant chemotherapy, surgery must occur within 56 days of finishing chemotherapy

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Eligibility Criteria

- Women ≥ 18 years of age.
- ECOG performance status of 0 or 1.
- Invasive breast cancer of any histology. No prior ipsilateral breast cancer (invasive or DCIS). Contralateral DCIS okay, no invasive.
- AJCC Stage IIa –IIIa . T4, N3 and involved internal mammary disease (N1b, N1c, and N2b) will not be allowed.
- Clinical N1 or N2 disease prior to induction chemotherapy are allowed if pathologically N0-N2 at the time of mastectomy.
- Treating physician must plan to deliver regional nodal radiation.
- Negative inked histologic margins of mastectomy.
- Chemo allowed neoadjuvant or adjuvant (before or after RT).
- Planned chest wall reconstruction is required with intent declared for autologous vs. implant and immediate vs. delayed reconstruction before randomization.
- Reconstruction can take place before or after post mastectomy radiation.

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Contact Us

Study Chair: Matthew M. Poppe, MD
E-mail: matthew.poppe@hci.utah.edu
Phone: 801-581-2396

Statistician: Jennifer Le-Rademacher, PhD
E-mail: Le-Rademacher.Jennifer@mayo.edu
Phone: 507-284-4402

Protocol Coordinator: Niveditha Subbiah
E-mail: niveditha@uchicago.edu
Phone: 773-702-9934

Data Manager: Misty Bova-Solem
E-mail: bovasolem.misty@mayo.edu

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