Cancer Research Consortium of West Michigan
P: 616.391.1230 | 800.336.6299 | www.crcwm.org

FAST FACTS

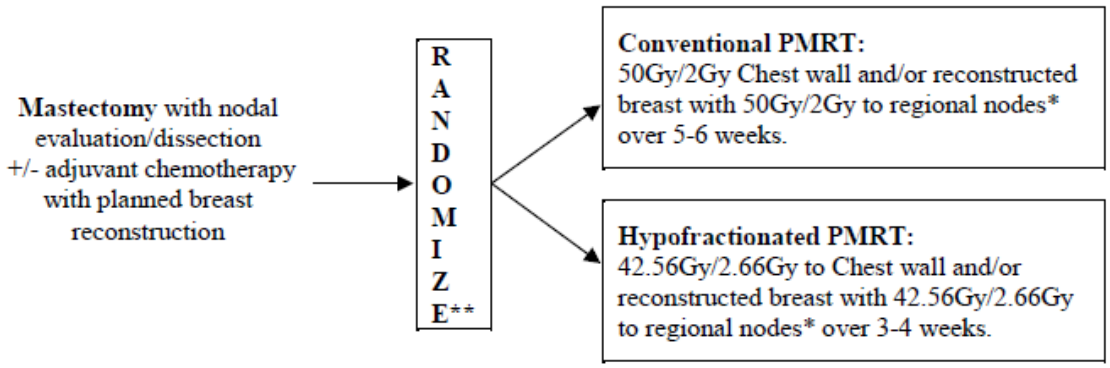
A221505: RT CHARM: PHASE III RANDOMIZED TRIAL OF HYPOFRACTIONATED POST MASTECTOMY RADIATION WITH BREAST RECONSTRUCTION

Eligibility Criteria

1. Histologically confirmed invasive carcinoma of the breast of any of the following histologies (ductal, lobular, mammary, medullary, or tubular). Patients with metaplastic breast cancer are not eligible.
2. Patients will be staged according to the TNM staging system.
   For patients not receiving neoadjuvant chemotherapy, pathologic staging must be T0N1-2a, T1N1-2a, T2N1-2a, T3N0-2a, and all M0 status.
   For patients receiving neoadjuvant chemotherapy, clinical pre-chemo staging and post mastectomy pathological staging is required for all patients. Patients who have received neoadjuvant chemotherapy and are pathologically cT0-2 and N0 are only eligible if biopsy-proven clinically N1 or N2 disease is documented prior to the start of neoadjuvant chemotherapy. cT3N0 patients or ypT3N0 patients who receive neoadjuvant chemotherapy may be eligible based on clinical or pathological T stage, and do not require pathologically positive lymph nodes.
   Note: Higher of the clinical or pathological T and N stage are used for final staging, if receiving neoadjuvant chemotherapy.
   All patients with clinical, radiographic or pathological T4, N3 or involved internal mammary disease (N1b, N1c, and N2b) are not eligible. N1 mic patients are eligible.
3. No prior therapeutic radiation therapy to the chest, neck or axilla. Prior radioactive oral iodine is permitted.
4. No prior history of ipsilateral breast cancer (invasive disease or DCIS). LCIS and benign breast disease is allowed.
5. No history of prior or concurrent contralateral invasive breast cancer. Benign breast disease, LCIS or DCIS of contralateral breast is allowed.
6. No active collagen vascular diseases, such as: systemic lupus erythematous, scleroderma, or dermatomyositis.
7. Negative inked histologic margins from mastectomy pathology (no invasive cells at margin). Patients with DCIS at margin are eligible.
8. No significant post mastectomy complications in the ipsilateral breast requiring an unplanned re-operation or admission for IV antibiotics. Re-operation for margins evaluation, nodal completion and routine reconstruction is acceptable.
9. Radiation oncologist intends to treat all target volumes described in section 7.4 and respect all normal tissues identified in section 7.4.3 in accordance with the dosimetric constraints described (simulation before registration recommended).
10. Radiation oncologist is planning to treat regional lymph nodes including internal mammary nodes and meet acceptable protocol dosimetric requirements.
11. Radiation oncologist is NOT planning to utilize a chest wall/scar boost.

12. Patient must have undergone immediate reconstruction at the time of mastectomy or be planning to undergo reconstruction within 18 months after radiation.
13. Treating physician and patient must plan to start radiation treatment within the timeframe specified in section 7.0.
14. If a tissue expander is utilized it needs to be a fluid filled expander, NO air expander (unless completely deflated) during radiation therapy.
15. For patients with diabetes, hemoglobin A1C test must have been performed ≤ 90 days prior to registration.
16. No co-existing medical conditions with life expectancy < 5 years.
17. No other malignancy within 5 years of registration with the exception of basal cell or squamous cell carcinoma of the skin treated with local resection only or carcinoma in situ of the cervix.
18. Negative pregnancy test (serum or urine β-HCG) in women of child-bearing potential ≤ 7 days prior to registration. Patients who have received a bilateral tubal ligation still require a negative pregnancy test for eligibility.
    A female of childbearing potential is a sexually mature female who has not undergone a hysterectomy or bilateral oophorectomy and has not been naturally postmenopausal for at least 12 consecutive months.
19. Women of child-bearing potential must agree to utilize a form of birth control or agree to undergo sexual abstinence during radiation therapy.
20. ECOG (Zubrod) Performance Status 0-1
21. Patient ≥ 18 years of age
22. Patients must be able to read and comprehend English, in order to be able to complete study questionnaires. However, patients participating through CCTG institutions who can read and comprehend French are eligible.

Schema



* Regional Nodes will include axilla (Levels 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.

** Patients will be stratified before randomization for immediate versus delayed and autologous versus implant only reconstruction. All reconstruction must be completed before radiation to be classified as immediate and autologous reconstruction is autologous tissue +/- implant.