RTOG 1014: A Phase II Study of Repeat Breast Preserving Surgery and 3D-Conformal Partial Breast Re-Irradiation (PBrI) for Local Recurrence of Breast Carcinoma

CTC v4.0; Staging Criteria 7th ed.; RECIST n/a

Patient Eligibility
1. Histopathologic confirmation via lumpectomy of local in-breast ipsilateral recurrence and final breast surgery (lumpectomy and/or final re-excision) within 42 days prior to study entry. Patients must have had an initial lumpectomy followed by whole breast radiation >1 year prior to study entry
2. Histology of the local in-breast recurrence consistent with invasive ductal, medullary, tubular, mucinous, lobular; or ductal carcinoma in situ
3. Ipsilateral breast mammogram and MRI within 120 days prior to study entry and contralateral breast mammogram done within 12 months of study entry
4. Recurrent tumor size ≤3 cm in greatest dimension on pathologic specimen
5. Negative histologic margins of resection, no tumor on ink, following breast-preserving surgery of local recurrence (Re-excision is permitted to achieve negative margins)
6. Estrogen/progesterone analysis performed prior to study entry
7. Axilla negative or ≤3 positive lymph nodes without extra capsular extension documented after evaluation - as described in section 8.1.15
8. Whole body PET-CT or all of the following: CT of the chest, abdomen, pelvis and bone scan within 120 days prior to study entry (metastatic work-up not necessary for DCIS recurrences)
9. For females of childbearing potential, negative serum pregnancy test ≤7 days prior to study entry
10. History and physical exam performed within 120 days prior to study entry
11. Zubrod Performance status 0-1
12. Age ≥18 years of age
13. The target lumpectomy cavity must be clearly defined and the target lumpectomy cavity1 whole breast reference volume must be <30% based on a postoperative, pretreatment CT scan
14. Patient must provide study specific informed consent prior to study entry

Patient Ineligibility
1. Pregnancy or women of childbearing potential who are sexually active and not willing/able to use medically acceptable forms of contraception
2. Women who are breast feeding
3. Evidence of multicentric ipsilateral breast recurrence or regional recurrence (other than axilla) documented by diagnostic mammography, breast ultrasound (optional), and/or breast MRI. Suspicious regions must be histologically proven negative to be eligible
4. Evidence of simultaneous distant recurrence documented by physical exam or radiographic evaluation in invasive recurrences
5. Clinical or radiographic evidence of metastatic disease in invasive recurrences
6. Patients with skin involvement
7. Prior invasive malignancy other than previous ipsilateral breast cancer and/or non-melanoma skin cancer unless disease free for a minimum of 3 years
8. Contralateral mastectomy
9. >3 positive axillary lymph nodes and/or metastatic axillary disease with extracapsular extension documented after evaluation - as described in section 8.1.15
10. Patients with Paget's disease of the nipple
11. Patients with a breast technically unsatisfactory for partial breast irradiation.
12. Chemotherapy administered <2 weeks prior to study entry and failing to recover from non-hematologic side effects ≤ grade 1
13. Patients with collagenous diseases, specifically systemic lupus erythematosus, scleroderma, or dermatomyositis
14. Patients with psychiatric or addictive disorders that would preclude obtaining informed consent
Pre-Study Parameters

Within 120 days of study entry

1. History and physical
2. CT chest/abdomen/pelvis, bone scan, ipsilateral mammogram and MRI, whole body PET/CT optional, breast ultrasound optional
3. Breast CT for treatment planning
4. Final breast surgery within 42 days of study entry (lumpectomy or re-excision).
5. Post-op breast exam
6. Performance status and pregnancy test (if applicable) within 7 days of study entry
7. Estrogen, progesterone, Her2 status (see sect 4.1 and 11.1 for detail and exceptions)

Treatment

Partial Breast Re-Irradiation (PBrI)
3D-Conformal External Beam
1.5 GY x 15 (BID) to 45 Gy Total