RTOG

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Country: USA

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Title: RTOG 9804: Phase III trial of observation ± tamoxifen *versus* RT ± tamoxifen for good risk duct carcinoma *in-situ* (DCIS) of the female breast.

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Summary:

- Opened in December 1999
- Target accrual 1790

Primary Objective:

- In the defined good-risk group, assess the role of whole breast radiation plus/minus tamoxifen compared to wide excision to negative margins alone plus/minus tamoxifen, in decreasing or delaying the appearance of local failure.

Secondary Objectives:

- In the defined good risk group, assess the role of whole breast radiation plus/minus tamoxifen compared to wide excision with negative margins alone plus/minus tamoxifen, in preventing the need for mastectomy.
- Assess distant disease free survival to affirm the hypothesis that the proportion of patients in either arm who fail with progression to invasive local disease can be successfully salvaged with further definitive local therapy and adjuvant systemic therapy as is appropriate to the individual case.
- Adopt a working pathology classification system for DCIS, which can be taught to and uniformly applied by the community pathologist. This will include processing the specimen, assessing extent of disease, margin assessment, and the grading of the lesion. Pathologic relationship of any calcium present to the DCIS will also be noted.
- Establish a registry for patients with an epidemiological questionnaire, for companion studies of biomarkers and genetics, to be done at a later time when research in this area has identified useful markers. Tissue and blood will be banked from each patient who agrees to participate in this aspect of the study.
- Establish a tissue bank of patients who progress to local failure in the study breast.

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Scheme:

Stratify

Age

1 <50
2 ≥50

Final path margins

1 Negative (re-excision)
2 3–9 mm
3 10 mm

Mammographic/pathologic size of primary

1 ≤1 cm
2 >1 cm to ≤2.5 cm

Nuclei grade

1 Low
2 Intermediate

Tamoxifen use

1 No
2 Yes

Randomize

Arm 1

Observation +/−tamoxifen 20 mg/day for 5 years

Arm 2

Radiation therapy* to the whole breast, ±tamoxifen 20 mg/day for 5 years

*RT Dose: 1.8 Gy per fraction × 28 fractions, for a total dose of 50.4 Gy; OR 2.0 Gy per fraction × 25 fractions, for a total dose of 50.0 Gy; OR 2.656 Gy per fraction × 16 fractions, for a total dose of 42.5 Gy.

Update:

- This is an intergroup study coordinated by RTOG with participation by CALGB, NCIC CTG and SWOG. In addition, this is an approved CTSU study, meaning that institutions from other cooperative groups may enter patients through the CTSU.
- Study closed 14 July 2006 due to slow accrual, with a total of 636 patients

Related Publications: None available

Topics:

- DCIS
- Radiotherapy

Keywords: DCIS, radiotherapy

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Title: NSABP B-39/RTOG 0413: A randomized phase III study of conventional whole breast irradiation (WBI) *versus* partial breast irradiation (PBI) for women with stage 0, I, or II breast cancer.

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Summary:

- Opened in March 2005
- Targeted accrual 3000

Primary Objective:

- To determine whether partial breast irradiation (PBI) limited to the region of the tumor bed following lumpectomy provides equivalent local tumor control in the breast compared to conventional whole breast (WBI) in the local management of early stage breast cancer.

Secondary Objectives:

- To compare overall survival, recurrence-free survival, and distant disease-free survival, between women receiving PBI and women receiving WBI.
- To determine whether PBI delivered in 5 treatment days can provide a comparable cosmetic result to WBI.
- To determine if perceived convenience of care is greater for women receiving PBI compared to women receiving WBI.
- To compare acute and late toxicities between the radiation therapy regimens.

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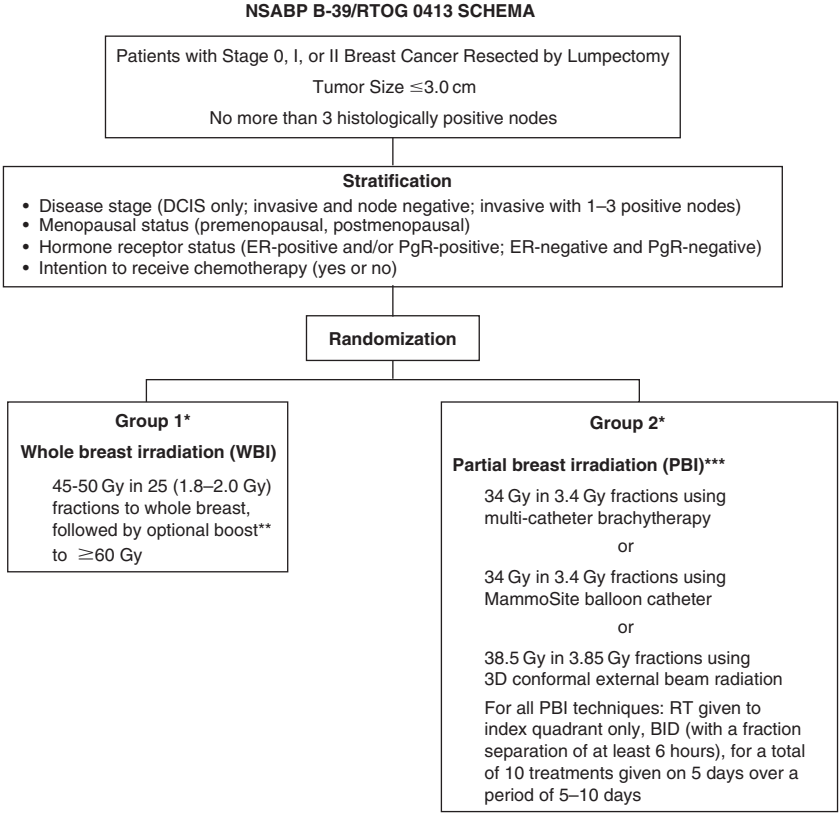
Scheme:



* See Section 15.0 of the protocol for instructions regarding chemotherapy and hormonal therapy. Chemotherapy, if given, will be administered before WBI and following PBI.

** Brachytherapy boost is not allowed (see Section 11.1.4. of the protocol).

*** The PBI technique utilized will be at the physicians discretion and will be based on technical considerations, radiation oncology facility technique credentialing (see Section 5.0 of the protocol), as well as patient preference.

Update:
- This is a joint study between NSABP and RTOG with participation from other cooperative groups. As of 2 April 2006, 1060 patients have been entered.

Related Publications: None available

Topics:
- Radiotherapy

Keywords: Partial breast irradiation

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Title: A phase II trial to evaluate three dimensional conformal radiation therapy (3D-RT) confined to the region of the lumpectomy cavity for stage I and II breast carcinoma.

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Summary:

- Opened in April 2003
- Closed in April 2004
- Total accrual = 58

Primary Objective:

- For selected patients with stage I and II breast carcinoma, 3D-CRT delivered to the region of the lumpectomy cavity is technically feasible and reproducible in a multi-institutional trial.

Secondary Objectives:

- To deliver 3D-CRT with acceptable complication rates.
- Cosmetic results after partial breast irradiation therapy following tylectomy will be comparable to that obtained after whole breast external beam radiation therapy.
- The local tumor control rate in the breast after partial breast irradiation therapy following tylectomy will be comparable to that of conventional external beam radiation therapy, with less inconvenience and potentially less cost to the patient, given the selection criteria which minimize the risk of clinically significant multicentric or extensive residual carcinoma following tylectomy.

Scheme:

Register

38.5 Gy total/10 fractions (3.85 Gy per fraction)
2 fractions/day (separated by 6 hours)
Given in 5 consecutive working days

Radiotherapy should begin within 8 weeks of surgery
(If chemotherapy is given first, RT begins 2 weeks after the last cycle of chemotherapy)

Update:

- The primary endpoint manuscript was published in 2006. Patients are continuing to be followed up for the efficacy endpoints.

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Related Publications: Vicini, F, Winter, K *et al*. A phase I/II trial to evaluate three-dimensional conformal radiation therapy confined to the region of the lumpectomy cavity for stage I/II breast carcinoma: initial report of feasibility and reproducibility of radiation therapy oncology group (RTOG) study 0319. *Int J Radiat Onco Biol Phys* 2005; 63: 1531–1537.

Topics:
- Radiotherapy

Keyword: 3D-CRT

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