

NSABP B-39/RTOG 0413

Eligibility – 1

Stage 0, I, or II, assuming

- Tumor
 - DCIS or invasive (ductal or lobular)
 - ≤ 3 cm
 - Final negative margins (no ink on tumor)
- Lymph nodes
 - 0-3 +LNs
 - - SLN
 - +SLN bx -> AND (total # LNs removed ≥ 6)
 - AND (# LNs removed ≥ 6)
 - No axillary staging needed for DCIS

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Eligibility – 2



Receptor Status

- Pre-randomization ER analysis
 - “borderline” will be considered +ve
- Pre-randomization PR analysis if ER-

Timing

- Pt **MUST** be randomized withing *42 days* of last breast/axillary surgery

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Eligibility – 3



Pre-randomization Volume Analysis

- CT of breast breast
- Contour
 - Whole breast reference volume
 - Lumpectomy
- Calculate ratio
 - Lumpectomy cavity volume \leq .30 (30%)
whole breast reference vol

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Eligibility – 4

Other

- **Consent signed**
- **≥ 18 y/o**
- **Prior malignancy OK if:**
 - CIS cervix, colon, melanoma
 - Basal and squamous skin cancer
 - No prior breast cancer – EVER!
 - Prior excised LCIS OK
- **Life expectancy > 10 years**
 - Excluding breast cancer prognosis

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Ineligibility - 1

- **Extracapsular nodal extension**
- **Any positive NON-axillary LN**
 - Note, intramammary LN staged as axilla
- **Palpable or radiographic findings concerning for disease outside of index lesion**
- **Metastatic disease**

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Ineligibility - 2

- **Anti-endocrine therapy for more than 28 days prior to randomization**
- **Any prior chemotherapy or XRT**
- **Breast implants**
- **Collagen-vascular disease**
- **Pregnancy**
- **Psychiatric/Addictive disorders**

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Whole Breast Reference Volume

Definition:

**All tissue within the boundaries of
standard whole breast tangential fields,
excluding lung.**

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Whole Breast Reference Volume

- **How to:**
 - Place pt in tx position/immobilization
 - Place markers around breast + medial/lateral tangent borders
 - CT from mandible-lung base
 - Slice thickness ≤ 5 mm
 - Simulate field sizes for tangents
 - Contour lumpectomy cavity and all tissue within tangent beams
 - Eliminate lung tissue from whole breast volume
 - Cavity:Breast $\leq 30\%$