The widespread utilization of screening mammography has led to a dramatic increase in the number of women diagnosed with DCIS. More than 54,000 women will be diagnosed this year in the United States. Clinical research has focused on optimizing control of the index lesion with minimal morbidity and in preventing the occurrence of new primary tumors. NSABP trials B-17 and B-24 demonstrated a stepwise improvement in local and contralateral tumor control with the use of breast radiotherapy and tamoxifen in women treated with lumpectomy, although a new analysis by Allred was presented at the San Antonio Breast Cancer Symposium demonstrating that the advantage to tamoxifen was observed only in women with detectable estrogen receptors. A new NSABP study and another trial in the United Kingdom will evaluate anastrozole in postmenopausal patients with DCIS, with the hope that tumor control will be improved with fewer side effects.

NSABP B-35: TAMOXIFEN VERSUS ANASTROZOLE IN POSTMENOPAUSAL PATIENTS WITH DUCTAL CARCINOMA IN SITU — Open Protocol
Projected Accrual: 3,000 Patients

Eligibility
Postmenopausal women with DCIS treated with lumpectomy, ER/PR-positive or borderline

Stratification: Age ≤60 versus >60

ARM 1 Tamoxifen 20 mg + placebo qd × 5 yrs + XRT

ARM 2 Anastrozole 1 mg + placebo qd × 5 yrs + XRT

Study Contact: Richard Margolese, Chair
National Surgical Adjuvant Breast and Bowel Project Tel: 412-330-4600

NSABP DCIS TRIALS: CUMULATIVE INCIDENCE OF INVASIVE AND NONINVASIVE EVENTS IN THE IPSILATERAL AND CONTRALATERAL BREAST

IBIS-II DCIS: INTERNATIONAL, MULTI-CENTRIC STUDY OF TAMOXIFEN VERSUS ANASTROZOLE IN POSTMENOPAUSAL WOMEN WITH DUCTAL CARCINOMA IN SITU (DCIS) — Open Protocol
Projected Accrual: 4,000 patients

Eligibility
Postmenopausal women, DCIS removed within last six months, ages 40-70

ARM 1 Tamoxifen 20 mg qd + placebo

ARM 2 Anastrozole 1 mg qd + placebo


PHASE III RANDOMIZED STUDY OF WHOLE BREAST RADIOTHERAPY VERSUS OBSERVATION WITH OR WITHOUT TAMOXIFEN IN WOMEN WITH GOOD-RISK DUCTAL CARCINOMA IN SITU OF THE BREAST — Open Protocol
Protocol Id: C88-NCC-489, C88-NCC-491, C89-NCC-494, C89-NCC-496
Projected Accrual: 1,790 patients

Eligibility DCIS ≤ 2.5 cm, no prior chemo or XRT or concurrent hormone treatment (except tamoxifen)

ARM 1 Observation with optional tamoxifen qd × 5 years

ARM 2 Radiotherapy daily 5 times per week for 3.5 – 5.5 weeks × optional tamoxifen qd × 5 years

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