The 1998 publication of the initial results of the NSABP P-1 trial brought the issue of chemoprevention in high-risk women to the forefront of attention in both the lay press and the medical literature. While tamoxifen reduced the incidence of breast cancer in high-risk women in both P-1 and the recently reported IBIS-I trial, NSABP P-2 (the STAR trial) is comparing another SERM (raloxifene) to tamoxifen in this setting. An updated 2002 ASCO Technology Assessment endorsed the implementation of additional research in chemoprevention. The recent presentation of the ATAC trial—demonstrating an advantage to anastrozole over tamoxifen in reduction of contralateral cancers—hints toward future trials of the aromatase inhibitors in a chemoprevention setting, such as the recently launched IBIS-II trial comparing anastrozole to a placebo. Ultimately, with a number of available effective agents, issues of toxicity and side effects may become paramount.

**CLINICAL TRIALS OF BREAST CANCER CHEMOPREVENTION**

**RANDOMIZED, PLACEBO-CONTROLLED CLINICAL TRIAL TO DETERMINE THE WORTH OF TAMOXIFEN FOR PREVENTING BREAST CANCER — Closed Protocol**

Protocol ID: BCPT-1, NCI-P91-0022, NSABP-P-1

**Eligibility**

- Pre- and postmenopausal women ≥ 35 years old at high risk for breast cancer
- Placebo x 5 years

**Eligibility**

- Placebo x 5 years

**arm 1**

- Tamoxifen 20 mg qd x 5 years

**arm 2**

- Placebo x 5 years


**STUDY OF TAMOXIFEN AND RALOXIFENE (STAR) FOR THE PREVENTION OF BREAST CANCER — Open Protocol**

Protocol ID: NSABP-P-2

**Projected Accrual** 22,000 women

**Eligibility**

- Postmenopausal women at risk (LCIS or ≥ 1.66% five-year probability) for developing breast cancer

**arm 1**

- Tamoxifen + placebo x 5 years

**arm 2**

- Raloxifene + placebo x 5 years

Quality of life assessed at baseline and six-month intervals to five years, then annually thereafter.

Study Contact: Norman Wolmark, Chalc. Tel: 412-359-3336
National Surgical Adjuvant Breast and Bowel Project

**source:** NCI Physician Data Query, February 2005

**INTERNATIONAL BREAST CANCER CHEMOPREVENTION STUDY — Closed Protocol**

Protocol ID: IBIS-1

**Eligibility**

- Women aged 35-70 at high risk for breast cancer
- Placebo x 5 years


**INTERNATIONAL BREAST CANCER CHEMOPREVENTION INTERVENTION STUDY 2 — Open Protocol**

Protocol ID: IBIS-2

**Projected Accrual** 6,000 women

**Eligibility**

- Increased breast cancer risk

**arm 1**

- Anastrozole 1 mg qd x 5 years

**arm 2**

- Placebo x 5 years


**SELECT PUBLICATIONS**


