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Title: NSABP B-35 – A clinical trial comparing anastrozole with tamoxifen in postmenopausal patients with ductal carcinoma in situ (DCIS) undergoing lumpectomy with radiation therapy.

Coordinator(s):
Principal Investigator: N. Wolmark

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Summary:
- Opened on 6 January 2003
- Target accrual: 3000 patients

Objectives:
- To compare the value of 1 mg/day of anastrozole to 20 mg/day of tamoxifen, each given for 5 years, in preventing the subsequent occurrence of breast cancer (local, regional and distant recurrences, and contralateral breast cancer) following lumpectomy with radiation therapy in postmenopausal women with ductal carcinoma in situ (DCIS).
- To compare the quality of life of the patients between the two arms.
- To compare the two arms in terms of osteoporotic fractures.
- To compare the two arms in terms of future malignancies.
- To compare the two arms in terms of disease free survival and overall survival.

Scheme:
Arm I: Tamoxifen + placebo + breast radiation therapy
Arm II: Anastrozole + placebo + breast radiation therapy

Update:
- 3104 patients have been accrued through June 2006.
- Patient accrual closed June 2006.

Related Publications:
None available

Topics:
- DCIS
- Postmenopausal patients
- Predictive markers
- Hormonal therapy
- Aromatase inhibitors
- Radiotherapy

Keywords:
DCIS, postmenopausal patients, predictive markers, hormonal therapy, aromatase inhibitors, radiotherapy
Title: **NSABP B-36** – A clinical trial of adjuvant therapy comparing six cycles of 5-fluorouracil, epirubicin and cyclophosphamide (FEC) to four cycles of adriamycin and cyclophosphamide (AC) in patients with node-negative breast cancer.

Coordinator(s):
Principal Investigator: N. Wolmark
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Summary:
- Opened to accrual on 20 May 2004
- Target accrual: 2700

**Objectives:**
- To determine superiority between four cycles of AC and six cycles of FEC for prolonging disease-free survival in women with node-negative breast cancer.
- To determine superiority among the proposed regimens for prolonging survival (S), recurrence-free interval (RFI), and distant recurrence-free interval (DRFI) in this population.
- To compare the adverse events between four cycles of AC and six cycles of FEC.
- To compare the adverse events within the proposed regimens administered with celecoxib or placebo in patients enrolled prior to suspension of celecoxib/placebo randomization on 17/12/04.
- To describe the differences in symptoms and quality of life between the chemotherapy regimens.
- To assess the rates of post-chemotherapy amenorrhea in premenopausal women.
- To examine the relationship between change in LVEF and self-reported physical functioning.
- To evaluate if six cycles of FEC is superior to four cycles of AC in cases in which HER-2 and/or Topo-II genes are amplified.

**Scheme:**
- *Arm 1:* Four cycles of adriamycin and cyclophosphamide
- *Arm 2:* Six cycles of 5-fluorouracil, epirubicin and cyclophosphamide

**Update:**
- 1625 patients have been accrued through September 2006.
Related Publications: None available

Topics:
- Node-negative breast cancer
- Predictive markers
- Cardiac function
- Menstrual cycle

Keywords: Node-negative breast cancer, predictive markers, cardiac function, menstrual cycle
Title: NSABP B-38 – A phase III, adjuvant trial comparing three chemotherapy regimens in women with node-positive breast cancer: docetaxel/doxorubicin/cyclophosphamide (TAC); dose-dense (DD) doxorubicin/cyclophosphamide followed by DD paclitaxel (DD AC→P): DD AC followed by DD paclitaxel plus gemcitabine (DD AC→PG).

Coordinator(s):
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Summary:
• Opened to accrual on 1 October 2004
• Target accrual: 4800

Objectives:
• To determine whether the dose-dense doxorubicin and cyclophosphamide followed by dose-dense paclitaxel plus gemcitabine regimen (DD AC→PG) is superior to the docetaxel, doxorubicin, and cyclophosphamide (TAC) regimen as well as to the dose-dense doxorubicin and cyclophosphamide (AC→)→dose-dense paclitaxel regimen (DD AC→P) in improving disease-free survival (DFS).
• To compare the relative DFS of docetaxel, doxorubicin, and cyclophosphamide (TAC) and dose-dense doxorubicin/ cyclophosphamide followed by dose-dense paclitaxel alone (DD AC→P).
• To determine whether the dose-dense doxorubicin/cyclophosphamide followed by dose-dense paclitaxel plus gemcitabine regimen is superior to the docetaxel, doxorubicin, and cyclophosphamide (TAC) regimen as well as dose-dense doxorubicin and cyclophosphamide followed by dose-dense paclitaxel regimen in improving survival (S), recurrence-free interval (RFI), and distant recurrence-free interval (DRFI).
• To compare S, RFI, and DRFI of the docetaxel, doxorubicin, and cyclophosphamide (TAC) and dose-dense doxorubicin and cyclophosphamide followed by dose-dense paclitaxel regimens (DD AC→P).
• To compare the toxicities of the three regimens.
Scheme: Arm 1: Doxorubicin, cyclophosphamide, and docetaxel once every 21 days for six visits.
Arm 2: Doxorubicin and cyclophosphamide through a vein once every 14 days for four visits. Fourteen days after the last treatment with these two chemotherapy drugs, patients will begin to receive paclitaxel once every 14 days for four visits.
Arm 3: Doxorubicin and cyclophosphamide through a vein once every 14 days for four visits. Fourteen days after the last treatment with these two chemotherapy drugs, patients will begin to receive paclitaxel and gemcitabine once every 14 days for four visits.

Update: • 3513 patients have been accrued through September 2006.

Related Publications: None available

Topics: • Dose densification
• Predictive markers
• Node-negative breast cancer
• Gemcitabine
• Anthracyclines
• Taxanes

Keywords: Dose densification, predictive markers, node-negative breast cancer, gemcitabine, anthracyclines, taxanes
**Title:** NSABP B-39 – 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.

**Coordinator(s):**

**Principal Investigator:**
N. Wolmark

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**Summary:**
- Opened to accrual 21 March 2005
- Target accrual: 3000

**Objectives:**
- To determine whether PBI limited to the region of the tumor bed following lumpectomy provides equivalent local tumor control in the breast compared to conventional WBI in the local management of early stage breast cancer.
- To compare PBI and WBI in terms of overall survival, recurrence free survival, distant disease-free survival, cosmetic results, fatigue and treatment-related symptoms, and perceived convenience of care.

**Scheme:**

*Arm 1:* Whole breast irradiation

*Arm 2:* Partial breast irradiation (multi-catherer brachytherapy, MammoSite, or 3D conformal external beam radiation)

**Update:**
- 2034 patients have been accrued through September 2006.

**Related Publications:**
None available

**Topics:**
- Radiation therapy
- Breast conservation treatment

**Keywords:** Radiation therapy, breast conservative treatment