

NSABP

Country: USA

Group: National Surgical Adjuvant Breast and Bowel Project
(NSABP)

Chair: N. Wolmark
National Surgical Adjuvant Breast and Bowel Project
East Commons Professional Building
Four Allegheny Center, 5th Floor
PITTSBURGH, PA 15212-5234
USA
Tel: +1 412 330 4600
Fax: +1 412 330 4660
Email: norman.wolmark@nsabp.org

Other Subgroup Head/Member(s): NSABP Operations Center
East Commons Professional Building
Four Allegheny Center, 5th Floor
PITTSBURGH, PA 15212-5234
USA

Chief Executive Officer: J. Goldberg
Tel: +1 412 330 4601
Fax: +1 412 330 4660
Email: joan.goldberg@nsabp.org

Chief Financial Officer: R. Jones
Tel: +1 412 330 4673
Fax: +1 412 330 4660
Email: ron.jones@nsabp.org

Associate Chair: M. O'Connell
Tel: +1 412 330 4600
Fax: +1 412 330 4660
Email: michael.oconnell@nsabp.org

Associate Chair/Director of Operations: D. Lawrence Wickerham
Tel: +1 412 330 4600
Fax: +1 412 330 4660
Email: larry.wickerham@nsabp.org

C. Geyer, Jr.
Tel: +1 412 330 4600
Fax: +1 412 330 4660
Email: charles.geyer@nsabp.org

Division of Membership Affairs: M. Ketner
Tel: +1 412 330 4624
Fax: +1 412 330 4661
Email: mary.ketner@nsabp.org

Division of Regulatory Affairs:	J. Mull Tel: +1 412 330 4625 Fax: +1 412 330 4661 Email: joyce.mull@nsabp.org
Clinical Coordinating Division:	L. Suhayda Tel: +1 412 330 4634 Fax: +1 412 330 4660 Email: lynne.suhayda@nsabp.org
Division of Protocol Development and Management:	B. Harkins Tel: +1 412 330 4643 Fax: +1 412 330 4660 Email: barbara.harkin@nsabp.org
Division of Scientific Publications:	B. Good Tel: +1 412 330 4639 Fax: +1 412 330 4660 Email: barbara.good@nsabp.org
Division of Public Relations and Communications:	L. Garvey Tel: +1 412 330 4621 Fax: +1 412 330 4645 Email: lori.garvey@nsabp.org
Division of Finance and Sponsored Projects:	D. Szczepankowski Tel: +1 412 330 4610 Fax: +1 412 330 4260 Email: donnas@nsabp.org
Other Subgroup Head/Member:	J. Costantino NSABP Biostatistical Center One Sterling Plaza 201 North Craig St., Suite 500 PITTSBURGH, PA 15213 USA Tel: +1 412 383 2638 Fax: +1 412 383 1387 Email: costan@nsabp.pitt.edu
Other Subgroup Head/Member:	W. Curran B-39 RTOG Group Chair American College of Radiology 1818 Market St., Suite 1600 PHILADELPHIA, PA 19103 USA Tel: +1 215 574 3189 Fax: +1 215 928 0153
Website:	www.nsabp.pitt.edu

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

N. Wolmark

Investigator:

National Surgical Adjuvant Breast and Bowel Project
 East Commons Professional Building
 Four Allegheny Center, 5th Floor
 PITTSBURGH, PA 15212-5234
 USA
 Tel: +1 412 330 4600
 Fax: +1 412 330 4660
 Email: norman.wolmark@nsabp.org

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

N. Wolmark

Investigator:

National Surgical Adjuvant Breast and Bowel Project

East Commons Professional Building

Four Allegheny Center, 5th Floor

PITTSBURGH, PA 15212-5234

USA

Tel: +1 412 330 4600

Fax: +1 412 330 4660

Email: norman.wolmark@nsabp.org

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):

Principal

N. Wolmark

Investigator:

National Surgical Adjuvant Breast and Bowel Project
 East Commons Professional Building
 Four Allegheny Center, 5th Floor
 PITTSBURGH, PA 15212-5234
 USA
 Tel: +1 412 330 4600
 Fax: +1 412 330 4660
 Email: norman.wolmark@nsabp.org

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 to 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

N. Wolmark

Investigator:

National Surgical Adjuvant Breast and Bowel Project

East Commons Professional Building

Four Allegheny Center, 5th Floor

PITTSBURGH, PA 15212-5234

USA

Tel: +1 412 330 4600

Fax: +1 412 330 4660

Email: norman.wolmark@nsabp.org

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-catherter 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