SWOG

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Title: Docetaxel and vinorelbine plus filgrastim with weekly trastuzumab for HER-2 positive, stage IV breast cancer.
S0215

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Summary: *Objectives:*

- To estimate 1 year survival in HER-2 positive stage IV breast cancer patients using a combination of docetaxel and vinorelbine with concurrent G-CSF support and weekly trastuzumab.
- To estimate the response rate (complete and partial, confirmed and unconfirmed) in the subset of patients with measurable disease.
- To estimate the progression-free survival in patients treated with this regimen.
- To estimate the qualitative and quantitative toxicities of this regimen.
- To obtain tissue blocks for the determination of predictors of response to microtubule interacting agents (such as β-tubulin mutations) and for other future studies.

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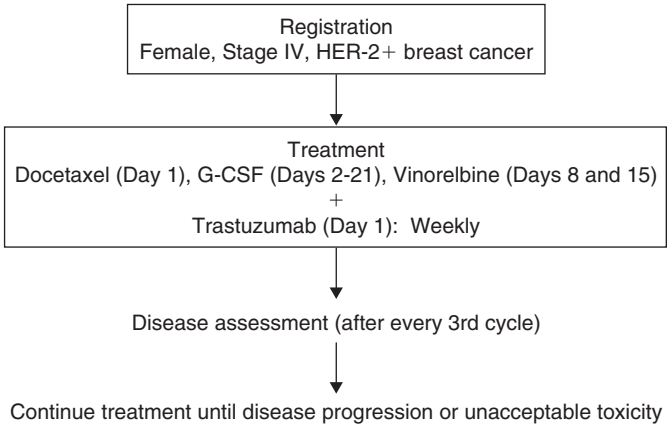
Scheme:



Update:

- To date, 51 of the planned 90 patients have been entered. Of 32 currently evaluated for toxicity, 13 (41%) have had grade three and 3 (9.4%) have had grade four toxicities. The latter were confined to neutropenia (2) and anemia (1). No febrile neutropenia or drug-related deaths have occurred to date. The study is expected to reach its accrual objectives within a year.

Related Publications:

Slamon D, Clark G, Wong S, *et al*. Human Breast Cancer: correlation of relapse and survival with amplificaiton of the HER-2/proto-oncogene. *Science* 1987; 235: 177–82.

Slamon D, Godolphin W, Jones L, *et al*. Studies of the HER-2/proto-oncogene in human breast and ovarian cancer. *Science* 1989; 244: 707–12.

Norton L, Slamon D, Leyland-Hones B, *et al*. Overall survival advantage of simultaneous chemotherapy plus the humanized anti-HER-2 monoclonal antibody, herceptin, in HER-2-overexpressing metastatic breast cancer. Proceedings of ASCO 1999; abst 483.

Baselga J, Norton L, Albanell J, *et al*. Recombinant humanized anti-HER-2 monoclonal antibody (Herceptin) enhances anti-tumor activity of paclitaxel and doxorubicin against HER-2/neu overexpressing human breast cancer xenografts. *Cancer Res* 1998; 58: 2825–31.

Konecny G, Pegram M, Beryt M, *et al*. Therapeutic advantage of chemotherapy drugs in combination with herceptin against human breast cancer cells with HER-2/neu overexpression. Proceedings of SABCS 1999, abst 467.

Topics:

- HER-2 positive patients
- Vinorelbine
- Trastuzumab

Keywords: Docetaxel, vinorelbine tartrate, filgrastim, trastuzumab

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Title: Phase III trial of continuous schedule AC + G versus q 2-week schedule AC, followed by paclitaxel given either q 2 weeks or weekly for 12 weeks as post-operative adjuvant therapy in node-positive or high-risk node-negative breast cancer.
S0221

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Summary: *Objectives:*

- To compare the disease-free survival of patients with node-positive or high-risk node-negative breast cancer treated with the combination of doxorubicin and cyclophosphamide given q 2 weeks with pegfilgrastim support with that of patients treated with weekly doxorubicin and daily oral cyclophosphamide with filgrastim support, with both treatments to be followed by paclitaxel given according to one of two schedules.
- To compare the disease-free survival of patients with node-positive or high-risk node-negative breast cancer treated with either 12 weeks of weekly paclitaxel or paclitaxel given q 2 weeks with pegfilgrastim support for six cycles following treatment with one of the two doxorubicin/cyclophosphamide regimens discussed above.
- To compare the overall survival produced by the four treatment arms.
- To compare the toxicity of the four treatment arms.
- To examine the association of putative prognostic markers with outcome and the interaction of these markers with treatment.

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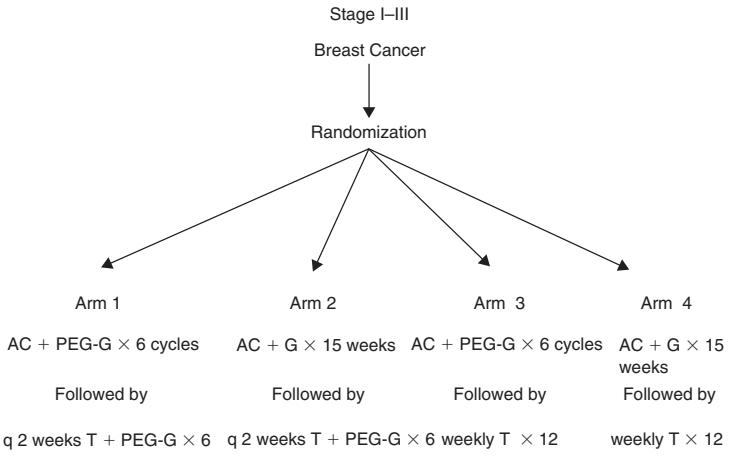
Scheme:



A = doxorubicin; C = cyclophosphamide; G = G-CSF; T = paclitaxel; PEG-G = pegfilgrastim

Update:

- Accrual on S0221 has been running at about 50 patients per month, with 60% of the registrations coming from SWOG institutions. Although it is the highest-accruing phase III study in SWOG, this rate is only about 30% of that which had been projected. Measures to improve accrual include the commitment of NCI-Canada to join the study (effective in 2006), and the allowance of entry for HER 2 positive patients (with added trastuzumab as per guidelines of N9831), until the new Intergroup trial for HER 2 positive patients is ready to open. In addition, the statistical design has been revised, and the total number required for entry will now be about 3000 rather than 4500, which should permit completion of the study within 5 years of its inception. Available information from a comparison of acute toxicities indicates that the q 2-week "AC" arm, with pegfilgrastim support, is associated with more grade 4 neutropenia than the "metronomic" arm with filgrastim (GCSF) support: 25% *versus* 6.8%, while hand-foot syndrome of grade 3 is less common on the q 2-week "AC" arm: 1.8% *versus* 12.4%. Mucositis of grade 3 is less common on the "AC" arms (6.7% *versus* 18%). One treatment-related death has been reported on each arm.

Related Publications:

Henderson I, Berry D, Demetri G, *et al*. Improved disease-free (dfs) and overall survival (os) from the addition of sequential paclitaxel (t) but not from the escalation of doxorubicin (a) dose level in the adjuvant chemotherapy of patients (pts) with node-positive primary breast cancer (bc). Proceedings of ASCO 1998; abst A390A.

Fisher B, Anderson S, Wickerham D, *et al*. Increased intensification and total dose of cyclophosphamide in a doxorubicin-cyclophosphamide

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regimen for the treatment of primary breast cancer: findings from National Surgical Adjuvant Breast and Bowel Project B-22. *J Clin Oncol* 1997; 15(5): 1858–69.

Fisher B, Anderson S, DeCillis A, *et al*. Further evaluation of intensified and increased total dose of cyclpphosphamide for the treatment of primary breast cancer: findings from National Surgical Adjuvant Breast and Bowel Project -25. J *Clin Oncol* 1999; 17(11); 3374–88.

Engelsman E, Klijn J, Rubens R, *et al*. "Classical" CMF versus a 3-weekly intravenous CMF schedule in postmenopausal patients with advanced breast cancer: an EORTC breast cancer cooperative group phase III trial (10808). *Eur J Cancer* 1991; 27(8): 966–70.

Topics:

- Node-negative breast cancer
- Node-positive breast cancer

Keywords: Cyclophosphamide, doxorubicin, filgrastim, pegfilgrastim, paclitaxel, trimethoprim sulphate

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Title: Phase III randomized trial of anastrozole versus anastrozole and fulvestrant as first line therapy for postmenopausal women with metastatic breast cancer.
S0226

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Summary: *Objectives:*

- To compare time to tumor progression in postmenopausal women with metastatic breast cancer treated with anastrozole *versus* anastrozole and fulvestrant.
- To compare clinical benefit (CR, PR, confirmed or unconfirmed, or stable disease ⩾24 weeks) and overall survival for this cohort of patients.
- To assess the adverse events of anastrozole as compared to anastrozole and fulvestrant in this cohort of patients.
- To assess the prognostic significance of subtypes of ER positivity and HER-2 status.
- To assess parameters of estrogen and clinical pharmacology and estrogen levels.
- To compare the anastrozole plasma levels on each treatment arm at 8, 16 and 24 weeks after randomization.
- To compare the estradiol serum levels on each treatment arm at baseline, 8, 16 and 24 weeks after randomization.

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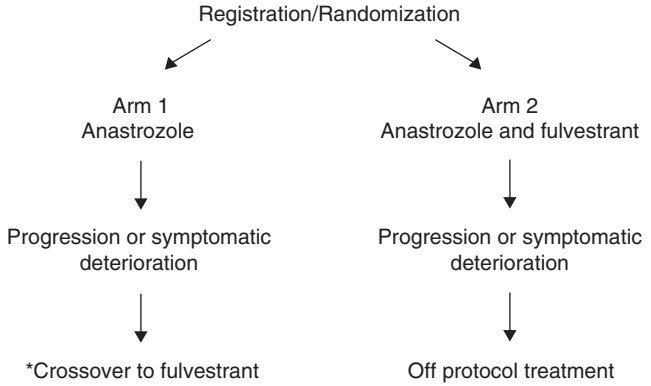

*Recommended for selected patients.

* Patients are strongly encouraged to "crossover" to treatment with fulvestrant alone if they are not candidates for immediate chemotherapy at the time of progression. Fulvestrant treatment will then follow the dose schedule and administration guidelines as provided in the S0226 protocol. For patients who are crossed over to treatment with fulvestrant, a standard prescription will be written to obtain fulvestrant.

Update:

- This study has underaccrued. A major reason for this is likely to be the requirement, initially built into the trial, that the first 100 patients entered had to undergo serial blood sampling for pharmacokinetic analysis of anastrozole plasma levels: that requirement has been dropped by amendment, after discussion with the pharmaceutical sponsors. A second measure which should substantially improve accrual is the participation by NCI-Canada on this trial nationwide, which is expected to take place in 2006. The study was recently discussed at the SWOG Data Safety and Monitoring Committee, and it was the recommendation of the Committee to continue accrual to the study, based on these considerations.

Related Publications:

Klijn J. Blamey R, Boccardo F, *et al*. Combined tamoxifen and luteinizing hormone-releasing hormone (LHRH) agonist versus LHRH agonist alone in premenopausal advanced breast cancer: a meta-analysis of four randomized trials. *J Clin Oncol* 2001; 19(2): 343–53.

Mouridsen H, Gershanovich M, Sun Y, *et al*. Superior efficacy of letrozole versus tamoxifen as first-line therapy for postmenopausal women with advanced breast cancer: results of a phase III study of the International Letrozole Breast Cancer Group. *J Clin Oncol* 2001, 19(10): 2596–606.

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Osborne C, Coronado-Heinsohn E, Hilsenbeck S, *et al*. Comparison of effects of a pure steroidal antiestrogen with those of ttamoxifen in a model of human breast cancer. *J Natl Cancer Inst* 1995; 87(10): 746–50.

Howell A, Robertson J, Aschermannova A, *et al*. Fulvestrant, formerly ICI 182,780, is as effective as anastrozole in postmenopausal women with advanced breast cancer progressing after prior endocrine treatment. *J Clin Oncol* 2002; 20(16): 3396–403.

Osborne C, Pippen J, Jones S, *et al*. Double-Blind, randomized trial comparing the efficacy and tolerability of fulvestrant versus anastrozole in postmenopausal women with adjuvant breast cancer progressing on prior endocrine therapy: Results of a North American Trial. *J Clin Oncol* 2002; 20(16): 3386–95.

Topics:

- Postmenopausal patients
- Metastatic breast cancer
- Prognostic factors

Keywords: Anastrozole, fulvestrant, surgery

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Title: Phase III trial of LHRH analog administration during chemotherapy to reduce ovarian failure following chemotherapy in early stage, hormone-receptor negative breast cancer.
S0230

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Summary: *Objectives:*

- The primary objective of this study is to compare the rate of premature ovarian failure at 2 years following standard adjuvant or neoadjuvant chemotherapy with or without the addition of ovarian suppression with a LHRH analog during chemotherapy in premenopausal women with early stage, hormone-receptor negative breast cancer.
- The secondary objectives are to compare rates of ovarian dysfunction at 1 and 2 years following standard adjuvant or neoadjuvant chemotherapy with or without ovarian suppression and to evaluate ovarian reserve in the two groups at 1 and 2 years. In addition, this study will describe pregnancy and other fertility information in the two groups after treatment and during the 5-year follow-up period.

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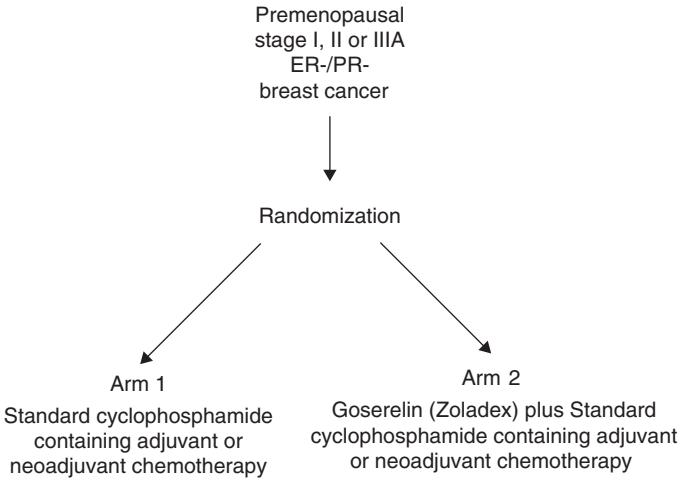
Scheme:



Update:

- This trial has suffered to date from underaccrual, raising concern about whether it can continue to successful completion. Efforts to address this problem focused first on other members of the Intergroup, with participation now by CALGB and ECOG. More recently, the European IBCSG has agreed to join the trial. Given the differences in patterns of practice between the US and Europe, it is hoped that participation by the Europeans will boost accrual substantially.

Related Publications:

Bines J, Oleske D, Cobleigh M, *et al*. Ovarian function in premenopausal women treated with adjuvant chemotherapy for breast cancer. *J Clin Oncol* 1996; 14(5): 1718–29.

Koyama H, Wada T, Nishiwasa Y. Cyclophosphamide-induced ovarian failure and its therapeutic significance in patients with breast cancer. *Cancer* 1977; 39: 1403–9.

Glode L, Robinson J, Gould S. Protection from cyclophosphamide-induced testicular damage with an analogue of gonadotropin-releasing hormone. *Lancet* 1981; 1: 1132–4.

Jordan V, Fritz N, Tormey D. Endocrine effects of adjuvant chemotherapy and long-term tamoxifen administration on node-positive patients with breast cancer. *Cancer Res* 1987; 47: 624–30.

Rivkees S, Crawford J. The relationship of gonadal activity and chemotherapy-induced gonadal damage. *JAMA* 1988; 259: 2123–5.

Topics:

- Hormone-receptor negative breast cancer
- Premenopausal patients
- Ovarian suppression

Keywords: Goserelin acetate, surgery

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Title: Phase III trial of bisphosphonates as adjuvant therapy for primary breast cancer.
S0307

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Summary: *Objectives:*

- To compare disease-free survival in patients receiving clodronate *versus* ibandronate *versus* zoledronic acid as adjuvant therapy for breast cancer.
- To compare overall survival in patients receiving clodronate *versus* ibandronate *versus* zoledronic acid as adjuvant therapy for breast cancer.
- To compare the distributions of sites of first recurrence on the three arms.
- To assess the adverse events of clodronate compared to ibandronate compared to zoledronic acid in this cohort of patients.
- To assess the association of PTHrP status and serum N-telopeptide levels at baseline with disease-free survival and sites of first recurrence.
- To test treatment-PTHrP and serum N-telopeptide levels interactions with respect to disease-free survival and sites of first recurrence.

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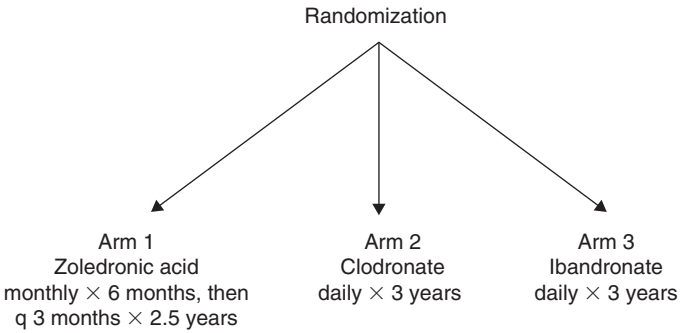
Scheme:



Patients will be followed for disease-free and overall survival, as well as sites of first recurrence.

Update:

- This study has just been activated. It will involve both the entire Intergroup and the NSABP.

Related Publications:

Coleman R, Rubens R. The clinical course of bone metastases from breast cancer. *Br J Cancer* 1987; 55(1): 61–6.

Lipton A, Theriault R, Hortobagyi G, *et al*. Pamidronate prevents skeletal complications and is effective treatment in women with breast carcinoma and osteolytic bone metastases. Cancer 2000; 88(5): 1082–90.

Paterson A, Powles T, Kanis J, *et al*. Double-blind controlled trial of oral clodronate in patients with bone metastases from breast cancer. *J Clin Oncol* 1993; 11(1): 59–65.

van Holten-Verzantvoort A, Kroon H, Bijvoet O, *et al*. Palliative pamidronate treatment in patients with bone metastases from breast cancer. *J Clin Oncol* 1993; 11(3): 491–8.

Major P, Lortholary A, Hon J, *et al*. Zoledronic acid is superior to pamidronate in the treatment of hypercalcemia of malignancy: a pooled analysis of two randomized, controlled clinical trials. *J Clin Oncol* 2001; 19(2): 558–67.

Topics:

- Bisphosphonates

Keywords: Clodronate, zoledronic acid, ibandronate, bisphosphonate

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Title: Phase II trial of simple oral therapy (continuous oral cyclophosphamide and capecitabine) in patients with metastatic breast cancer.
S0430

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Summary: *Objectives:*

- To evaluate the response rate (complete and partial, confirmed and unconfirmed) to combination simple oral therapy with cyclophosphamide and capecitabine (CC) in the treatment of metastatic breast cancer in the subset of patients with measurable disease.
- To estimate progression-free survival and overall survival in this population treated with this combination.
- To evaluate the toxicity of this drug combination in metastatic breast cancer.
- To explore the use of MUC-1 antigens (CA 27-29 or CA 15-3) as a surrogate for clinical benefit in patients with non-measurable disease.
- To develop a whole blood and serum repository for patients with metastatic breast cancer for future correlative studies.

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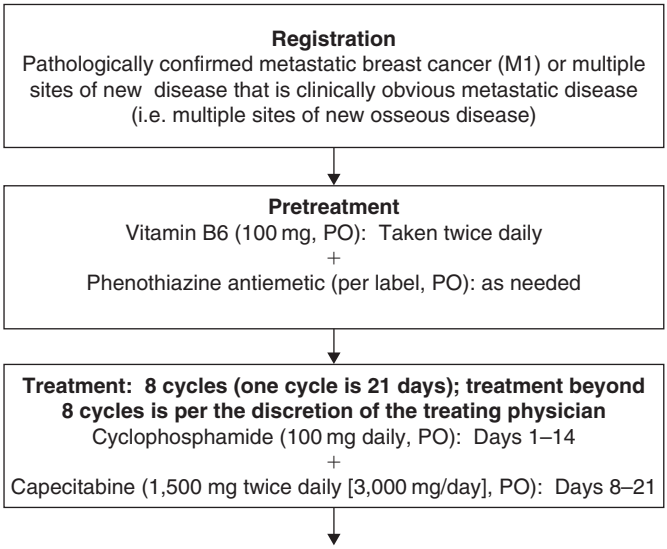
Scheme:



Update:

- To date, 51 of the planned 96 patients had been registered to this study. Six patients are ineligible for the following reasons: four due to disease not satisfying protocol requirements, one due to too many prior chemotherapy regimens, and one due to baseline MUC-1 antigen not within allowed timeframe. Four additional patients that are currently ineligible due to missing baseline data are included in the tables with the eligible patients. Among 13 patients evaluated for toxicity, two experienced Grade 3 lymphopenia.

Related Publications:

Lui G, Franssen E, Fitch M, *et al*. Patient preferences for oval versus intravenous palliative chemotherapy. *J Clin Oncol* 1997; 15(1): 110–15.

Hainsworth J, Burris H, Erland J, *et al*. Phase I trial of docetaxel administered by weekly infusion in patients with advanced refractory cancer. *J Clin Oncol* 1998; 16(6): 2164–8.

Hainsworth J, Burris H, Yardley D, *et al*. Weekly docetaxel in the treatment of elderly patients with advanced breast cancer: a Minnie Pearly Cancer Research Network phase II trial. *J Clin Oncol* 2001; 19(15): 3500–5.

Sawada N, Ishikawa T, Fukase Y, et al. Induction of thymidine phosphorylase activity and enhancement of capecitabine efficacy by taxol/taxotere in human cancer xenografts. *Clin Cancer Res* 1998; 4(4): 1013–19.

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Toi M, Bando H, Hiriguchi S, *et al*. Modulation of thymidine phosphorylase by neoadjuvant chemotherapy in primary breast cancer. *Br J Cancer* 2004; 90(12): 2338–43.

Topics:

- Capecitabine
- Metastatic breast cancer

Keywords: Capecitabine, cyclophosphamide

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Title: A phase II study of goserelin plus anastrozole for the treatment of male patients with hormone-receptor positive metastatic or recurrent breast cancer.
S0511

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Summary: *Objectives:*

- To assess progression-free survival (PFS) in male patients with hormone-receptor positive advanced breast cancer treated with the combination of goserelin and anastrozole.
- To assess the overall survival in these patients, and overall objective tumor response rate (confirmed and unconfirmed, complete and partial response) in the subset of these patients with measurable disease.
- To explore the association of prostate specific antigen (PSA), testosterone, estradiol (E2), estrone, estrone sulfate, follicle-stimulating hormone (FSH), luteinizing hormone (LH), and dehydroepiandrosterone (DHEA) levels, with PFS and response.
- To assess toxicity of the drug combination.
- To develop a tissue and serum repository for males with metastatic breast cancer for future correlative studies.

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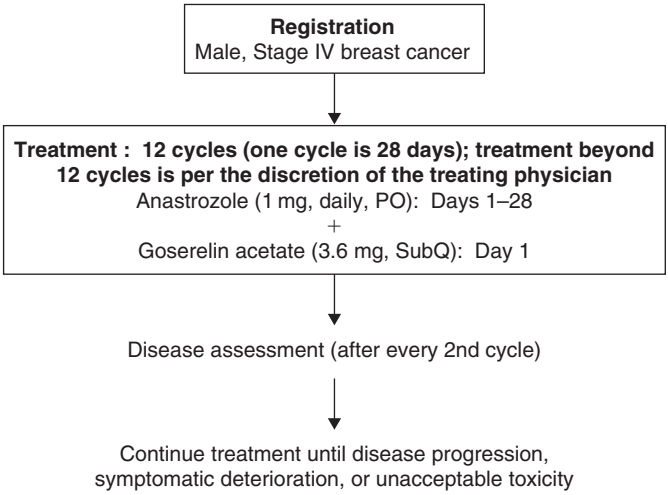
Scheme:



Update:

- This study has just opened.

Related Publications:

Giordano S, Cohen D, Buzdar A, *et al*. Breast carcinoma in men: a population-based study. *Cancer* 2004; 101(1): 51–7.

Anderson W, Althuis M, Brinton L, *et al*. Is male breast cancer similar or different than female breast cancer? *Breast Cancer Res Treat* 2004; 83(1): 77–86.

Giordano S, Buzdar A, Hortobagyi G, *et al*. Breast cancer in men. *Ann Intern Med* 2002; 137(8): 678–87.

Goss P, Reid C, Pintilie M, *et al*. Male breast carcinoma: a review of 229 patients who presented to the Princess Margaret Hospital during 40 years: 1955–1996. *Cancer* 1998; 85(3): 333–9.

Wang-Rodriguez J, Cross K, Gallagher S, *et al*. Male breast carcinoma: correlation of ER, PR, Ki-67, HER-2/neu, and p53 with treatment and survival, a study of 65 cases. *Mod Pathol* 2002; 15(8): 853–61.

Topics:

- Hormone-receptor positive breast cancer
- Metastatic breast cancer

Keywords: Anastrozole, goserelin acetate, male breast cancer

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Title: Randomized placebo-controlled biomarker modulation trial using celecoxib in premenopausal women at high risk for breast cancer. Phase IIb.
S0300

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Summary: *Objectives:*

- To assess whether mammographic density is reduced in women at high risk of breast cancer taking celecoxib as compared to high-risk woman taking placebo after 1 year of treatment.
- To assess whether proliferation as measured by Ki67 staining of breast epithelial cells is reduced in women at high risk of breast cancer taking celecoxib as compared to high-risk woman taking placebo after 1 year of treatment.
- To explore the difference in the expression of other biomarkers in breast tissue obtained from women treated with celecoxib as compared to tissue obtained from women treated with placebo. Additional biomarkers to be examined include the COX-2 enzyme and a marker of apoptosis in breast tissue.
- To assess whether IGF-1, IGFBP-3, and PGE2 plasma levels are altered in women at high risk of breast cancer taking celecoxib as compare to woman taking placebo after 1 year of treatment.
- To collect and bank serum and plasma from women at high risk of breast cancer prior to and after treatment with celecoxib for future biomarker analysis.
- To assess the toxicity of celecoxib compared to placebo in this setting.

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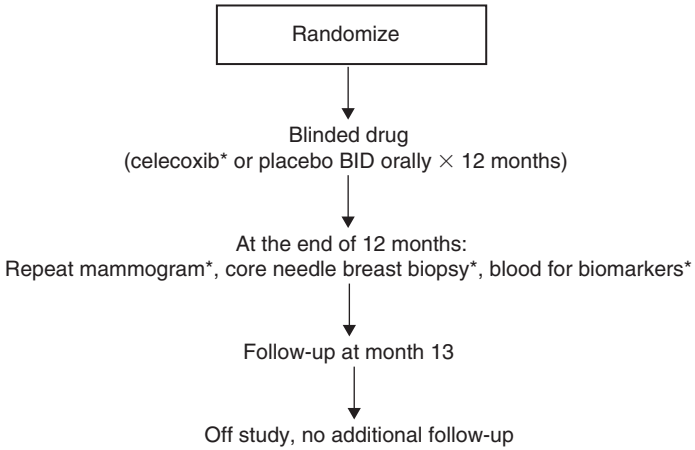
Scheme:

Baseline mammogram*, core needle breast biopsy*, blood for biomarkers*



*patients must not ake other non-steoidal anti-flammatory drugs while receiving treatment with celecoxib.

Update:

- This study has recently opened.

Related Publications:

Fisher B, Constantino J, Wickerham D, *et al*. Tamoxifen for prevention of breast cancer: report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998; 90(18): 1371–88.

Lippman S, Brown P. Tamoxifen precention of breast cancer: an instance of the fingerpost. *J Natl Cancer Inst* 1999; 91(21): 1809–19.

Osborne C. Tomoxifen in the treatment of breast cancer. *N Engl J Med* 1998; 339(22): 1609–18.

Pollard M, Luckert P. Indomethacin treatment of rats with dimethylhydrazine-induced intestinal tumors. *Cancer Treat Rep* 1980; 64: 1323–7.

Reddy B, Rao C, Rivenson A, *et al*. Inhibitory effect of aspirin on azoxymethane-induced colon carcinogenesis in F344 rats. *Carcinogenesis* 1993; 14(8): 1493–7.

Topics:

- Celecoxib
- Premenopausal patients

Keywords:

Celecoxib, cancer control

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