

BC Cancer Protocol Summary for Neoadjuvant or Adjuvant Therapy for Breast Cancer using Exemestane in Postmenopausal Women

Protocol Code

BRAJEXE

Tumour Group

Breast

Contact Physician

Dr. Susan Ellard

ELIGIBILITY:

- May be given preoperatively in postmenopausal women with hormone receptor positive breast cancer who are unsuitable for immediate surgery or preoperative chemotherapy
- Only for postmenopausal women (no menses for greater than 12 months; check FSH, LH, estradiol levels if less than 55 and prior hysterectomy or uncertain menopausal status due to young age or other factors) with hormone receptor positive invasive breast cancer for the following indications:
 - **Upfront use for 5 years**
 - Early switch: Following 2-3 years of adjuvant tamoxifen (early switch) to complete 5 years of hormone blockade
 - Late switch: Following 4.5-6 years of adjuvant tamoxifen, remaining free of relapse, within less than 12 months of end of tamoxifen therapy; currently approved for up to 3 additional years of hormone blockade
 - Contraindications to tamoxifen or intolerant of tamoxifen

See Cancer Management Guidelines for [current guidelines](#).

EXCLUSIONS:

- premenopausal women
- DCIS only

TESTS

Baseline: bone density before or after 2-3 month trial of therapy

Biannual: bone density

If clinically indicated: serum cholesterol, triglycerides

TREATMENT:

Upfront Therapy:

exemestane 25 mg PO daily x 5 years

Early Switch following 2-3 years of tamoxifen:

exemestane 25 mg PO daily x 3-2 years **(total treatment time of 5 years)**

Late Switch following 4.5-6 years of tamoxifen

exemestane 25 mg PO x 3 years

PRECAUTIONS:

1. Hepatic dysfunction: Aromatase inhibitors are considered safe in mild-to-moderate hepatic dysfunction but have not been studied in severe hepatic dysfunction.
2. Bone density: The long-term effects of aromatase inhibitors on bone density in adjuvant therapy patients are unknown. Supplementation with calcium and vitamin D and regular weight bearing exercise is recommended. A bisphosphonate should be considered if clinically indicated. Caution in patients with an already established diagnosis of clinically significant osteoporosis.
3. Hyperlipidemia: An increase in cholesterol or triglyceride levels may occur when an aromatase inhibitor is initiated. Levels may need to be checked during the first few months of therapy, especially in those patients with prior significant lipid elevations.

Contact Dr. Susan Ellard or tumour group delegate at (250) 712-3900 or 1-888-563-7773 with any problems or questions regarding this treatment program.

References¹⁻⁶

1. Coombes RC, Hall E, Gibson LJ, et al. A randomized trial of exemestane after two to three years of tamoxifen therapy in postmenopausal women with primary breast cancer. *N Engl J Med* 2004;350(11):1081-92.
2. The ATAC Trialists' Group. Anastrozole Alone or in Combination with Tamoxifen versus Tamoxifen Alone for Adjuvant Treatment of Postmenopausal Women with Early-Stage Breast Cancer. *Cancer* 2003;98:1802-10.
3. The ATAC Trialists' Group. Anastrozole alone or in combination with tamoxifen versus tamoxifen alone for adjuvant treatment of postmenopausal women with early breast cancer: first results of the ATAC randomised trial. *Lancet* 2002;359(9324):2131-39.
4. The ATAC Trialists' Group. Results of the ATAC (Arimidex, Tamoxifen, alone or in combination) trial after completion of 5 years' adjuvant treatment for breast cancer. *Lancet* Published online December 8, 2004;364(9451).
5. Winer EP, Hudis C, Burstein HJ, et al. American Society of Clinical Oncology technology assessment on the use of aromatase inhibitors as adjuvant therapy for postmenopausal women with hormone receptor-positive breast cancer: status report 2004. *J Clin Oncol* 2005;23(3):619-29.
6. Goss PE, Ingle JN, Martino S, et al. A randomized trial of letrozole in postmenopausal women after five years of tamoxifen therapy for early-stage breast cancer. *N Engl J Med* 2003;349(19):1793-802.