

BC Cancer Protocol Summary for Therapy for Advanced Breast Cancer using a LHRH Agonist and an Aromatase Inhibitor

Protocol Code

BRAVLHRHA

Tumour Group

Breast

Contact Physician

Dr. Vanessa Bernstein

ELIGIBILITY:

- Premenopausal women (defined as those who have menstruated in the last 12 months or who are biochemically premenopausal) with locally advanced inoperable or metastatic endocrine receptor positive breast cancer.

TESTS:

If clinically indicated: serum cholesterol, triglycerides

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
letrozole	2.5 mg daily	PO
or		
anastrozole	1 mg daily	PO
or		
exemestane	25 mg daily	PO
buserelin long acting (SUPREFACT DEPOT)*	6.3 mg every 6 weeks x 2 treatments then every 8 weeks	subcutaneous
or		
goserelin long acting (ZOLADEX)*	3.6 mg every 4 weeks	subcutaneous
or		
leuprolide long acting (LUPRON DEPOT)*	7.5 mg every 4 weeks	IM

- Continue treatment until disease progression. Strongly consider surgical oophorectomy in responding patients.

*Once response has been established, the following long-acting agents may be substituted at the physician's discretion. Menstrual function, and if necessary, hormone levels can be monitored to ensure effective dosing.

Drug	Dose	BC Cancer Administration Guideline
buserelin long acting (SUPREFACT DEPOT)*	9.45 mg every 12 weeks	subcutaneous
or goserelin long acting (ZOLADEX LA)*	10.8 mg every 12 weeks	subcutaneous
or leuprolide long acting (LUPRON DEPOT)*	22.5 mg every 12 weeks	IM

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 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.

Call Dr. Vanessa Bernstein or tumour group delegate at (250) 519-5500 or 1-800-670-3322 with any problems or questions regarding this treatment program.

References:

1. Klijn JG, Beex LV, Mauriac L, et al. Combined treatment with buserelin and tamoxifen in premenopausal metastatic breast cancer: a randomized study. *J Natl Cancer Inst* 2000;92(11):903-11.
2. Klijn JGM, Blamey RW, 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.
3. Gnant M, Mlineritsch B, Schippinger W, et al. Endocrine Therapy plus zoledronic acid in premenopausal breast cancer. *N Engl J Med* 2009; 360:679-91.
4. Masuda N, et al. Monthly versus 3-monthly goserelin acetate in premenopausal patients with estrogen receptor positive early breast cancer. *Breast Cancer Res Treat.* 2011;126(2):443-51.