

# BCCA Protocol Summary for Adjuvant Therapy for Breast Cancer Using a LHRH Agonist and Tamoxifen

**Protocol Code**

*BRAJLHRHT*

**Tumour Group**

*Breast*

**Contact Physician**

*Dr. Stephen Chia*

## **ELIGIBILITY:**

- premenopausal women (defined as those who have menstruated in the last three months or who are biochemically premenopausal)
- estrogen or progesterone receptor positive
- node positive/high risk node negative patients who have turned down recommended adjuvant chemotherapy or
- low risk node negative patients for whom goserelin and tamoxifen would be a reasonable alternative to chemotherapy

## **EXCLUSIONS:**

- Patients with a history of significant thromboembolic disease

## **TESTS:**

- Annually: gynecological exam

## **TREATMENT:**

<b>Drug</b>	<b>Dose</b>	<b>BCCA Administration Guideline</b>
Tamoxifen	20 mg daily x 5 years	PO
Buserelin (base) depot (SUPREFACT DEPOT®)* or Goserelin (ZOLADEX®)* or Leuprolide (LUPRON®)*	6.3 mg every 6 weeks x 2 treatments then every 8 weeks x 3 years  3.6 mg every 4 weeks x 3 years  7.5 mg every 4 weeks x 3 years	SC  SC  IM

**Surgical oophorectomy should be strongly considered in older pre-menopausal women who do not want to preserve their fertility and who are tolerating the menopausal side effects of therapy.**

**\*Once response has been established, the following long-acting agents may be substituted at the physician's discretion for a total of 3 years of therapy. Menstrual function, and if necessary, hormone levels can be monitored to ensure effective dosing.**

Buserelin (base) depot (SUPREFACT DEPOT®) or Goserelin (ZOLADEX®) or Leuprolide (LUPRON®)	9.45 mg every 12 weeks  10.8 mg every 12 weeks  22.5 mg every 12 weeks	SC  SC  IM
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**PRECAUTIONS:**

1. **Myelosuppression:** Mild myelosuppression with transient thrombocytopenia may occur rarely. The association with tamoxifen is uncertain.
2. **Endometrial Cancer:** Annual gynecologic examinations are recommended. Pelvic complaints, such as unusual vaginal bleeding, require prompt evaluation.
3. **Ocular Toxicity:** Ocular toxicity is rare and may occur after only a few weeks of therapy, although it is more common with prolonged treatment. Ophthalmologic examination is recommended if visual disturbances occur.
4. **Thromboembolism:** Tamoxifen is associated with an increased risk of thromboembolism that is comparable to estrogen replacement therapy.
5. **Hepatotoxicity:** While hepatotoxicity is rare and usually presents as elevated hepatic enzymes, more serious liver abnormalities have been reported.
6. **Hyperlipidemia:** Elevations in cholesterol and triglycerides may occur in patients with pre-existing hyperlipidemias.

**Call Dr. Stephen Chia or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.**

Date activated: 1 June 2006 (replacing BRAJGT)

Date revised: 1 May 2009 (unsafe abbreviations and symbols replaced)

**References:**

1. Jakesz R, Hausmaninger H, Kubista E, et al. Randomized adjuvant trial of tamoxifen and goserelin versus cyclophosphamide, methotrexate and fluorouracil: Evidence for the superiority of treatment with endocrine blockade in pre-menopausal patients with hormone-responsive breast cancer – Austrian Breast and Colorectal Cancer Study Group Trial 5. J Clin Oncol 20:4621-27, 2002
2. Boccardo F, Rubagotti A, Amoroso D, et al. Cyclophosphamide, methotrexate, and fluorouracil versus tamoxifen plus ovarian suppression as adjuvant treatment of estrogen receptor positive pre/perimenopausal breast cancer patients: results of the Italian Breast Cancer Adjuvant Study Group 02 Randomized Trial J Clin Oncol 18:2718-87, 2000

3. Jonat, W, Kaufmann M, Sauerbrei W, et al. Goserelin versus cyclophosphamide, methotrexate and fluorouracil as adjuvant therapy in pre-menopausal patients with node positive breast cancer. The Zoladex Early Breast Cancer Research Association Study. J Clin Oncol 20:4628-35, 2002