BC Cancer Protocol Summary for Palliative Therapy for Breast Cancer using a LHRH agonist and Tamoxifen

Protocol Code	*BRAVLHRHT*
Tumour Group	*Breast*
Contact Physician	*Dr. Nathalie Levasseur*

ELIGIBILITY:

- Premenopausal women (defined as those who have menstruated in the last 12 months or who are biochemically premenopausal) with metastatic breast cancer whose tumour expresses either the estrogen or progesterone receptor (or whose ER/PR status is unknown but who have had a disease free interval of over two years from initial diagnosis)
- Patients may have had prior adjuvant chemotherapy or adjuvant tamoxifen if breast cancer recurred greater than 1year since coming off adjuvant tamoxifen

EXCLUSIONS:

- Prior endocrine treatment for advanced disease
- Patients with a history of significant thromboembolic disease

TESTS:

- If clinically indicated: CBC & Diff, platelets, creatinine, total bilirubin, ALT, alkaline phosphatase, GGT, LDH, calcium, albumin, CA 15-3
- Annually: gynecological exam (patients with an intact uterus)

TREATMENT:

Drug	**Dose**	**BC Cancer Administration Guideline**
tamoxifen	20 mg daily	PO
goserelin long acting (ZOLADEX)** or leuprolide long acting (LUPRON DEPOT)**	3.6 mg every 4 weeks 7.5 mg every 4 weeks	subcutaneous IM

Continue 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**
goserelin long acting (ZOLADEX LA) or leuprolide long acting (LUPRON DEPOT)	10.8 mg every 12 weeks 22.5 mg every 12 weeks	subcutaneous IM

Warning: The information contained in these documents are a statement of consensus of BC Cancer professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is at your own risk and is subject to BC Cancer's terms of use available at www.bccancer.bc.ca/terms-of-use.

PRECAUTIONS:

1. **Flare Response:** A transient increase in bone pain, local disease flare (swelling and redness) and/or hypercalcemia may occur when treatment is initiated. Hypercalcemia is more likely with bone metastases and may require aggressive treatment (see supportive care protocol SCHYPCAL).
2. **Myelosuppression:** Mild myelosuppression with transient thrombocytopenia may occur rarely. The association with tamoxifen is uncertain.
3. **Endometrial Cancer:** Annual gynecologic examinations are recommended. Pelvic complaints, such as unusual vaginal bleeding, require prompt evaluation.
4. **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.
5. **Thromboembolism:** Tamoxifen is associated with an increased risk of thromboembolism that is comparable to estrogen replacement therapy.
6. **Hepatotoxicity:** While hepatotoxicity is rare and usually presents as elevated hepatic enzymes, more serious liver abnormalities have been reported.
7. **Hyperlipidemia:** Elevations in cholesterol and triglycerides may occur in patients with pre-existing hyperlipidemias.

Call Dr. Nathalie Levasseur or tumour group delegate at (604) 877-6000 or 1-800-663-3333 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.

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