

BC Cancer Protocol Summary for the Adjuvant Treatment of Resected Ductal Carcinoma In Situ using Tamoxifen

Protocol Code

BRAJLDTAM

Tumour Group

Breast

Contact Physician

Dr. Nathalie LeVasseur

ELIGIBILITY:

Patients must have:

- Fully resected hormone receptor-positive ductal carcinoma in situ (DCIS)

Notes:

- Tamoxifen should be started within 12 weeks of last treatment (definitive surgery or radiation)
- Patients who completed last treatment (definitive surgery or radiation) on or after 1 May 2023, and have not progressed, are eligible for BRAJLDTAM if all other eligibility criteria are met,
- Patients with microinvasive DCIS are eligible for either BRAJLDTAM or BRAJTAM per provider discretion

EXCLUSIONS:

Patients must not have:

- Hormone receptor-negative DCIS,
- History of venous thromboembolism (VTE)

CAUTION:

- Advanced liver disease

TESTS:

- If clinically indicated: CBC & Diff, platelets, serum cholesterol, triglycerides, total bilirubin, alkaline phosphatase, ALT, GGT

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
tamoxifen	10 mg every other day	PO

Continuously for up to 3 years of treatment unless disease progression or unacceptable toxicity.

PRECAUTIONS:

1. **Myelosuppression:** Mild myelosuppression with transient thrombocytopenia may occur rarely. The association with tamoxifen is uncertain.
2. **Endometrial Cancer:** Annual gynecological 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. **Ovulation Induction:** Tamoxifen may induce ovulation in pre- and peri-menopausal women. Barrier forms of contraception are highly recommended. Women should not become pregnant while taking tamoxifen, as there is positive evidence of human fetal risk.
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) 930-2098 or 1-800-663-3333 with any problems or questions regarding this treatment program.

References:

1. DeCensi A, Puntoni M, Guerrieri-Gonzaga A, et al. Randomized Placebo Controlled Trial of Low-Dose Tamoxifen to Prevent Local and Contralateral Recurrence in Breast Intraepithelial Neoplasia. *J Clin Oncol*. 2019 Jul 1;37(19):1629-1637.
2. Floren LC, Hebert MF, Venook AP, Jordan VC, Cisneros A, Somberg KA. Tamoxifen in liver disease: potential exacerbation of hepatic dysfunction. *Ann Oncol*. 1998 Oct;9(10):1123-6.