

BCCA Protocol Summary for Palliative Therapy for Metastatic Breast Cancer Using Testosterone Enanthate

Protocol Code

BRAVTEST

Tumour Group

Breast

Contact Physician

Dr. Susan Ellard

ELIGIBILITY:

- Fifth line hormonal treatment of metastatic breast cancer in postmenopausal women.

EXCLUSIONS:

- Breast cancer in males
- Hypercalcemia
- Consider risk-benefit in cardiac, renal or hepatic disease

TESTS:

- Prior to each dose until stable or if clinically indicated: hemoglobin
 - If clinically indicated: serum calcium* and albumin (or ionized calcium), alkaline phosphatase
- *corrected calcium (mmol/L) = total calcium (mmol/L) + (0.02 x [40 – albumin in g/L])

PREMEDICATIONS:

- None required

TREATMENT:

Drug	Dose	BCCA Administration Guideline
testosterone enanthate (DELATESTRYL®)*	400 mg (2 mL) every 4 weeks	IM

*5 mL multidose vial containing 200 mg/mL

- An appropriate dose in women increases hemoglobin by 10-20 g/L with minimal or no virilization (i.e., voice deepening if acceptable to the patient).
- Continue treatment for at least 3 months to allow time for a response. Discontinue if disease becomes progressive again. If clinical circumstances allow for an observation period, observe for rebound regression.

DOSE MODIFICATIONS:

1. Dose Escalation

- Escalate dose by one level if there is insufficient hemoglobin rise with no virilization and no evidence of a response.

Level	Dose
standard	400 mg (2 mL) IM every 4 weeks
increase 1 level	400 mg (2 mL) IM every 3 weeks
increase 2 levels	400 mg (2 mL) IM every 2 weeks

2. Dose Reduction

- Reduce dose by one level if there is significant edema, unacceptable virilization or excessive increase in hemoglobin.

Level	Dose
standard	400 mg (2 mL) IM every 4 weeks
decrease 1 level	300 mg (1.5 mL) IM every 4 weeks
decrease 2 levels	200 mg (1 mL) IM every 4 weeks

PRECAUTIONS:

- Hypercalcemia:** Androgen therapy may worsen hypercalcemia due to metastatic breast cancer.
- Tumour growth stimulation:** Androgen therapy occasionally accelerates disease progression. Close monitoring is required, especially during the early stages of therapy.
- Virilization:** Some effects such as voice changes or clitoromegaly may not be reversible. The patient and physician must decide how much virilization will be tolerated before dose reducing or discontinuing. To prevent virilization, discontinue when signs of mild virilization appear and before the process becomes irreversible.
- Injection site reactions:** IM injections of androgens have been associated with local urticarial and injection reactions (induration, furunculosis).

Call 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.

Date activated: 01 Nov 2001 (replaces fluoxymesterone)

Date revised: 01 May 2009 (unsafe abbreviations and symbols replaced,
physician contact revised)