

NCCTG N10C2 - Double-Blind, Placebo-Controlled Study of Magnesium Supplements to Reduce Menopausal Hot Flashes

Fast Facts

CTCAE v.4

Magnesium/placebo provided.

Inclusion Criteria

1. Age \geq 18 years.
2. Women with a history of breast cancer (currently without malignant disease).
3. Botherome hot flashes (defined by their occurrence \geq 28 times per week and of sufficient severity to make the patient desire therapeutic intervention).
4. Presence of hot flashes for \geq 30 days prior to study registration.
5. Women who are postmenopausal as defined by (1) absence of a period in the past 12 months; or (2) bilateral oophorectomy.
Note: Women with at least one ovary but without a uterus should be deemed postmenopausal by either (1) age over 55 or (2) a combination of estrogen within a postmenopausal range (per local lab) and FSH over 40 mIU/mL.
6. Calculated or measured (Cockcroft and Gault formula) creatinine clearance $>$ 30 mL/minute
7. Ability to complete questionnaire(s) by themselves or with assistance.
8. ECOG Performance Status (PS) 0 or 1.
9. Willingness to provide the biologic specimens as required by the protocol (see Sections 6.17, 14.0).
10. Provide informed written consent.

Exclusion Criteria

1. Any of the following current (\leq 28 days prior to registration) or planned therapies (tamoxifen, raloxifene, or aromatase inhibitors are allowed, but the patient must have been on a constant dose for \geq 28 days and must not be expected to stop the medication during the study period):
 - Antineoplastic chemotherapy (Note: trastuzumab or lapatinib are allowed)
 - Androgens
 - Estrogens (any delivery route)
 - Progestational agents
2. History of prior use of magnesium for hot flashes.
3. Current or planned use of gabapentin (for any reason) or antidepressants (for any reasons) or other agents for treating hot flashes (except stable dose of vitamin E is allowed as long as they were started $>$ 30 days prior to study registration and are to be continued through the study period. Soy is allowed, if it is planned to be continued at the same dose during the study period).
4. History of allergic or other adverse reaction to magnesium.
5. Current use of magnesium for any indication (except one standard multiple vitamin dose is allowed per day).
6. Diabetes (because diabetes can be associated with magnesium wasting); or taking diuretics, corticosteroids, bile acid sequestrants and other prescription and over the counter medications that may affect magnesium levels.
7. Current (\leq 7 days prior to registration) or planned use of other non-drug therapies for managing hot flashes, such as acupuncture or yoga (use of these therapies for other reasons is allowed).
8. Patients with conditions that are implicated in decreased absorption of magnesium (e.g., Crohn's disease, ETOH abuse).
9. Patients who have diarrhea where magnesium might make it worse (per provider discretion).
10. Women of childbearing potential, premenopausal women.

Pre-study Parameters

1. History and physical including height, weight and performance status
2. Serum Creatinine, serum magnesium during week 1

Treatment

