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OT2-07-02: SWOG S0927: A Randomized Double Blind Placebo-Controlled Trial of Omega-3-Fatty Acid for the Control of Aromatase Inhibitor (AI)-Induced Musculoskeletal Pain in Women with Early Stage Breast Cancer.

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Article

Info & Metrics

Abstracts: Thirty-Fourth Annual CTRC-AACR San Antonio Breast Cancer Symposium-- Dec 6-10, 2011; San Antonio, TX

Abstract

Background: Despite the well-proven efficacy of aromatase inhibitors(AIs) for the treatment of hormone-sensitive breast cancer, a significant number of women suffer from musculoskeletal side-effects which can result in early discontinuation of this important medication. Given the proposed anti-inflammatory effects of omega-3-fatty acid and the paucity of therapeutic options for AI-induced arthralgia, it is therefore reasonable to test the efficacy of omega-3-fatty acid in women with breast cancer who have developed moderate to severe joint symptoms after initiating AIs.

Specific aims: To assess if omega-3-fatty acid as compared to placebo causes a reduction in worst joint pain/stiffness in women with AI-associated arthralgias at 12weeks as measured by the modified Brief Pain Inventory (BPI). Additional measures will include the WOMAC, M-SACRAH, FACT-ES and global rating of change, which will be assessed at baseline, 6, 12 and 24 weeks. We will evaluate fasting lipids, hormone levels, serum inflammatory markers (TNF, IL2, CRP), and markers of joint destruction (CTX-II) at baseline, 12 and 24 weeks.

Eligibility criteria: Pts. must have histologically-confirmed stages I-III breast cancer, with no evidence of metastatic disease and undergone definitive breast cancer surgery. Pts must be post-menopausal and currently be taking a third-generation AI —anastrozole(Arimidex®), letrozole (Femara®), or exemestane (Aromasin®) for at least the previous 90 days prior to registration with plans to continue for at least an additional 180 days after registration. The patient must have a worse joint pain/stiffness score of 5 or greater on the 10-point scale of the BPI which started or increased after initiation of AI. Pts must not have taken omega-3-fatty acid supplements within the past 3 months prior to registration. Pts will be randomized to receive 6 capsules daily (at 1,000 mg each; ~600mg combination of ethyl esters EPA/DHA) of omega-3-fatty acid or matching placebo daily for 24 weeks. **Statistical methods:** We stipulate an $\alpha=0.05$ two-sided test, with an estimated 5% non-adherence and 20% dropout rate at the primary endpoint evaluation time of 12 weeks after randomization. For a two point difference in worst joint pain/stiffness and a 3.5 point SD at 12 weeks, 222 eligible patients would be required for 90% power under a two-arm normal design. To allow ineligibility rate of 10%, 246 total pts will be enrolled. The study should be activated September 2011. **Funding:** Supported by National Cancer Institute grant CA037429

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