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The effect of supraphysiologic levels of iodine on patients with cyclic mastalgia

Jack H Kessler [1]

Affiliations

Affiliation

1 Symbollon Pharmaceuticals, Inc., Framingham, Massachusetts 01702, USA. Jack_Kessler@Symbollon.com

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Abstract

A randomized, double-blind, placebo-controlled, multicenter clinical trial was conducted with 111 otherwise healthy euthyroid women with a history of breast pain. Patients had to document moderate or severe breast pain by recording a score > or =5 on a visual analog scale (VAS) of pain for > or =6 days per cycle and had to present with fibrosis involving at least 25% of both breast surfaces. Subjects could not be effectively treated with more conservative measures such as local heat or nonprescription analgesics. There was not a statistically significant difference in the dropout rate for patients on placebo (11.8%), 1.5 mg/day (31.3%), 3.0 mg/day (18.4%), or 6.0 mg/day (25%) of molecular iodine for 6 months. Physicians assessed breast pain, tenderness, and nodularity each cycle; patients assessed breast pain and tenderness with the Lewin breast pain scale at 3-month intervals and with a VAS at each cycle. A statistically significant improvement ($p < 0.01$) associated with dose was observed in the Lewin overall pain scale for all treated groups compared to placebo. Reductions in all three physician assessments were observed in patients after 5 months of therapy in the 3.0 mg/day (7/28; 25%) and 6.0 mg/day (15/27; 18.5%) treatment groups, but not the 1.5 mg/day or placebo group. Patients recorded statistically significant decreases in pain by month 3 in the 3.0 and 6.0 mg/day treatment groups, but not the 1.5 mg/day or placebo group; more than 50% of the 6.0 mg/day treatment group recorded a clinically significant reduction in overall pain. All doses were associated with an acceptable safety profile. No dose-related increase in any adverse event was observed.

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