Topics: Omega-6, evening primrose oil (EPO), gamma-linolenic acid (GLA, breast pain, mastalgia, premenstrual syndrome (PMS)

Objective: To evaluate the effectiveness of vitamin E, EPO and a combination of Vitamin E and EPO for pain control in women with cyclical mastalgia (breast pain associated with the menstrual cycle).

Background: The incidence of cyclical mastalgia reportedly ranges from 4-69% and involves breast swelling and tenderness during the luteal phase of the menstrual cycle, lasting about 7 days and resolving upon menstruation. About 70% of women are affected by breast pain at some point during their life. In some, resolution is achieved through use of support bras, over the counter pain medications and in severe conditions hormone therapies. Adverse effects associated with some of these medications make alternative natural therapies including EPO more appealing. In the past Efamol EPO was recommended as a first line treatment for mastalgia and was sold by prescription as a treatment for breast pain under the brand name Efamast.

Method: This randomized, double-blind, placebo-controlled clinical trial conducted at two US academic medical centres included 85 women with cyclical breast pain. Inclusion criteria included premenopausal, at least age 18, cyclical mastalgia defined as pain occurring within two weeks of menses onset, relieved by menses and that had occurred during at least two consecutive cycles, received no benefit from use of support bras, physician assurance after one month and a score of 3 or greater on a breast-pain scale from 1 to 10. Exclusion criteria were pregnancy or lactation, use of Vitamin E (>200 IU daily) or EPO in the previous two weeks, regular use of aspirin, non-steroidal anti-inflammatory drugs or anti-coagulant therapy, use of hormone therapies in the previous 3 months and prior diagnosis of breast cancer.

Before enrolment, a baseline history of breast and gynaecological health was obtained and a clinical breast examination was performed. A modified McGill Pain Questionnaire was completed at enrolment and after six months of treatment with either 1200 IU/day of Vitamin E, 3000 mg/day EPO, a combination of 1200 IU vitamin E + 3000 mg/day EPO or a corn oil placebo.

Findings: Intent-to-treat analysis showed a statistically significant difference in worst-pain improvement with the treatments EPO (P =0.005), Vitamin E (P=0.04) and EPO plus Vitamin E (p=0.05), but no difference with placebo (P=0.93). A two sample t-test showed a non-significant decrease in mastalgia individually for the three treatment options compared with placebo. The lack of significance was attributed to small sample size since only 41 patients completed the study (with no difference in the drop out rates between the four groups). The data were also analysed with the separation test by Aickin, which showed a trend towards a reduction of cyclical mastalgia with vitamin E and EPO individually and in combination.

Conclusion: Daily doses of 3000 mg EPO, 1200 IU of Vitamin E or a combination of the two for six months may decrease the severity of cyclical mastalgia.

Relevance to: Efamol Evening Primrose Oil

PRESS RELEASE

EPO proven again to relieve breast pain – after all these years!

An independent study by the Mayo Clinic in Rochester, Minnesota in collaboration with the University of Minnesota, Twin Cities, USA has confirmed what Efamol reported over two decades ago – EPO relieves symptoms of cyclical mastalgia [breast pain associated with premenstrual syndrome (PMS)]. This randomized, double-blind, placebo-controlled trial included 85 women with cyclical breast pain. Before enrolment, a baseline history of breast and gynaecological health was obtained and a clinical breast examination was performed. Following that, a modified McGill Pain Questionnaire was completed at enrolment and after six months of treatment with either 1200 IU/day of Vitamin E, 3000 mg/day EPO, a combination of 1200 IU vitamin E + 3000 mg/day EPO or a corn oil placebo. The pain questionnaire addressed pain by using 15 descriptors that represent the sensory and affective dimension of the pain experience as well as describing the pain in relation to the menstrual cycle, what relieves and increases the pain and an anatomical drawing to indicate the location of the painful area.

Analysis of the data confirmed a statistically significant difference in worst-pain improvement with EPO treatment alone, Vitamin E treatment alone or the two treatments combined, but no difference with placebo. Another analysis using a two sample t-test showed a non-significant decrease in mastalgia individually for the three treatment options compared with placebo. This lack of significance was attributed to small sample size since only 41 patients completed the study even though there was no difference in the drop out rates between the four groups. The data were also analysed with a Separation Test which showed a trend towards symptom reduction with vitamin E and EPO individually and in combination.

The results of this study confirm numerous historical reports where Efamol EPO reduced breast pain symptoms in clinical trials as well as in patients in clinical settings2-8. A 1992 paper published in the Journal of the Royal Society of Medicine and reviewing 17 years of experience in treating Breast Pain in the Cardiff Mastalgia Clinic in Wales advised that “Unless the severity of symptoms requires a rapid response, evening primrose oil should be considered as a first line treatment” (rather than hormone therapies that achieve similar results but with unwanted side effects)9. In 1999, a similar statement appeared in the Australian and New Zealand Journal of Surgery where researchers reported a 97 % response rate following 6 months of treatment with no significant side effects and recommended EPO be used “as a first-line specific treatment for Oriental women with disturbing cyclical mastalgia”10. Open trial using EPO for premenstrual syndrome have reported improvements in breast discomfort symptoms, and also symptoms of irritability, anxiety, depression, headache, fluid retention and tiredness.10,11 During the 1990s, Efamol EPO, sold under the brand name Efamast was licensed specifically for the treatment of breast pain and sold by prescription in at least three countries including the UK and Australia. Nearly two decades on, independent researchers have again confirmed benefits of EPO supplementation in a small study and are recommending completion of a large scale clinical trial to substantiate those findings.

References: