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**Abstract**

**OBJECTIVE:** To assess the clinical efficacy and adverse effects of gamma-linolenic acid (GLA), a plant seed oil-derived unsaturated fatty acid that suppresses inflammation and joint tissue injury in animal models, in the treatment of active rheumatoid arthritis (RA).

**METHODS:** Fifty-six patients with active RA were randomized to treatment groups in a 6-month, double-blind trial of GLA versus placebo. This was followed by a 6-month, single-blind trial during which all patients received GLA. Patients were treated with 2.8 gm/day of GLA as the free fatty acid or with sunflower seed oil (placebo) administered in identical capsules.

**RESULTS:** Treatment with GLA for 6 months resulted in statistically significant and clinically relevant reductions in the signs and symptoms of disease activity in patients with RA. Overall meaningful responses (at least 25% improvement in 4 measures) were also better in the GLA treatment group (14 of 22 patients versus 4 of 19 in the placebo group;  $P = 0.015$ ). During the second 6 months, both groups exhibited improvement in disease activity. Thus, patients taking GLA during the entire study showed progressive improvement during the second 6 months. In this group, 16 of 21 patients showed meaningful improvement at 12 months compared with study entry.

**CONCLUSION:** GLA at doses used in this study is a well-tolerated and effective treatment for active RA. GLA is available as a component of several plant seed oils and is usually taken in far lower doses than were used in this trial. It is not approved in the United States for the treatment of any condition, and should not be viewed as therapy for any disease. Further controlled studies of its in RA are warranted.

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