

# A randomized, double-blind, placebo-controlled study of growth hormone in the treatment of fibromyalgia

Am J Med. 1998 Mar;104(3):227-31.

Bennett RM, Clark SC, Walczyk J.

**PURPOSE:** The cause of fibromyalgia (FM) is not known. Low levels of insulin-like growth factor 1 (IGF-1), a surrogate marker for low growth hormone (GH) secretion, occur in about one third of patients who have many clinical features of growth hormone deficiency, such as diminished energy, dysphoria, impaired cognition, poor general health, reduced exercise capacity, muscle weakness, and cold intolerance. To determine whether suboptimal growth hormone production could be relevant to the symptomatology of fibromyalgia, we assessed the clinical effects of treatment with growth hormone.

**METHODS:** Fifty women with fibromyalgia and low IGF-1 levels were enrolled in a randomized, placebo-controlled, double-blind study of 9 months' duration. They gave themselves daily subcutaneous injections of growth hormone or placebo. Two outcome measures--the Fibromyalgia Impact Questionnaire and the number of fibromyalgia tender points--were evaluated at 3-monthly intervals by a blinded investigator. An unblinded investigator reviewed the IGF-1 results monthly and adjusted the growth hormone dose to achieve an IGF-1 level of about 250 ng/mL.

**RESULTS:** Daily growth hormone injections resulted in a prompt and sustained increase in IGF-1 levels. The treatment (n=22) group showed a significant improvement over the placebo group (n=23) at 9 months in both the Fibromyalgia Impact Questionnaire score (P <0.04) and the tender point score (P <0.03). Fifteen subjects in the growth hormone group and 6 subjects in the control group experienced a global improvement (P <0.02). There was a delayed response to therapy, with most patients experiencing improvement at the 6-month mark. After discontinuing growth hormone, patients experienced a worsening of symptoms. Carpal tunnel symptoms were more prevalent in the growth hormone group (7 versus 1); no other adverse events were more common in this group.

**CONCLUSIONS:** Women with fibromyalgia and low IGF-1 levels experienced an improvement in their overall symptomatology and number of tender points after 9 months of daily growth hormone therapy. This suggests that a secondary growth hormone deficiency may be responsible for some of the symptoms of fibromyalgia.