

Abstract

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Effect of glucosamine sulfate with or without omega-3 fatty acids in patients with osteoarthritis.

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INTRODUCTION: A total of 177 patients with moderate-to-severe hip or knee osteoarthritis (OA) were tested over a period of 26 weeks in a two-center, two-armed, randomized, double-blind, comparison study. The aim was to see if a combination of glucosamine sulfate (1500 mg/day) and the omega-3 polyunsaturated fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) (group A), showed equivalence (noninferiority) or superiority as opposed to glucosamine sulfate alone (group B).

METHODS: The primary therapy evaluation was performed using the Western Ontario and McMaster Universities Arthrosis index (WOMAC) score. At the end of the study, a reduction in the pain score of $>$ or $=20\%$ was required (primary target criterion) and the quantitative difference in the WOMAC subscores pain, stiffness, and function were analyzed (secondary target criteria).

RESULTS AND CONCLUSION: When a minimal pain reduction of $>$ or $=20\%$ was chosen, there was no statistically significant difference in the number of responders between the two groups (92.2% group A, 94.3% group B). A higher responder criterion ($>$ or $=80\%$ reduction in the WOMAC pain score) was chosen. Therefore, the frequency of responders showed a therapeutic and statistical superiority for the combination product of glucosamine sulfate and the omega-3 polyunsaturated fatty acids in patients who complied with the study protocol (group A 44%, group B 32%; $P=0.044$). OA symptoms (morning stiffness, pain in hips and knees) were reduced at the end of the study: by 48.5%-55.6% in group A and by 41.7%-55.3% in group B. The reduction was greater in group A than in group B. There was a tendency toward superiority shown in the secondary target criteria and concurrent variables. In the global safety evaluation, both products have been demonstrated to be very safe in long-term treatment over 26 weeks. To our knowledge, this is the first clinical trial in which glucosamine was given in combination with omega-3 fatty acids to patients with OA.

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