

Abstract

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Oral magnesium oxide prophylaxis of frequent migrainous headache in children: a randomized, double-blind, placebo-controlled trial.

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OBJECTIVE: To assess whether, in children, oral magnesium oxide reduces migrainous headache frequency, severity, and associated features compared to placebo.

BACKGROUND: There is no single, safe, widely well-tolerated, and effective prophylactic treatment for all children and adolescents with frequent migrainous headache.

DESIGN AND METHODS: Randomized, double-blind, placebo-controlled, parallel-group trial. This study was conducted between June 1997 and January 2000 using 7 selected Northern California Kaiser Permanente sites. We recruited children of ages 3 to 17 years who reported a 4-week history of at least weekly, moderate-to-severe headache with a throbbing or pulsatile quality, associated anorexia/nausea, vomiting, photophobia, sonophobia, or relief with sleep, but no fever or evidence of infection. Subjects were randomly assigned to receive either magnesium oxide (9 mg/kg per day by mouth divided 3 times a day with food) (n = 58) or matching placebo (n = 60) for 16 weeks. The number of headache days (days with at least one headache) during each of eight 2-week intervals was chosen to be the primary outcome variable.

RESULTS: Of those enrolled, 86 (73%) completed the study (42 received magnesium oxide and 44 placebo); 74 of 192 eligible subjects declined to participate. Baseline information on demographic factors, health status, and headache history was similar comparing the 2 groups. By intention-to-treat analysis, we found a statistically significant decrease over time in headache frequency in the magnesium oxide group (P = .0037) but not in the placebo group (P = .086), although the slopes of these 2 lines were not statistically significantly different from each other (P = .88). The group treated with magnesium oxide had significantly lower headache severity (P = .0029) relative to the placebo group.

CONCLUSIONS: This study does not unequivocally determine whether oral magnesium oxide is or is not superior to placebo in preventing frequent migrainous headache in children, but treatment with the active agent did lead to a significant reduction in headache days. Larger trials involving this safe, appealing complementary therapy are needed.

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