

Abstract

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A randomized double-blind placebo-controlled trial of thioctic acid in migraine prophylaxis.

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BACKGROUND: Impaired mitochondrial phosphorylation potential may play a role in migraine pathogenesis. Metabolic enhancers, such as riboflavin or coenzyme Q, are effective in migraine prophylaxis and quasi-devoid of adverse effects. Thioctic acid (-lipoic acid) is another substance known to enhance energy metabolism in mitochondria and to be beneficial in diabetic neuropathy.

OBJECTIVE: After an open pilot study suggesting its therapeutic antimigraine potentials, we embarked therefore in a randomized controlled trial of thioctic acid (Thioctacid) in migraine prophylaxis steered by the Belgian Headache Society.

METHODS: Five Belgian centers recruited 54 migraineurs (43 migraine without aura, 11 with aura; mean age 38 +/- 8 years; 7 males). After a 1-month single-blinded run-in period, 44 patients received either placebo (n = 18) or thioctic acid 600 mg p.o./day (n = 26) for 3 months.

RESULTS: Statistical analysis was carried out on an intention-to-treat basis. Monthly attack frequency tended to be reduced between run-in and the 3rd month of treatment in the thioctic acid group compared to placebo (P= .06). The proportion of 50% responders was not significantly different between thioctic acid (30.8%) and placebo (27.8%). Within-group analyses showed a significant reduction of attack frequency (P= .005), headache days (P= .009), and headache severity (P= .03) in patients treated with thioctic acid for 3 months, while these outcome measures remained unchanged in the placebo group. No adverse effects were reported. For logistical reasons this trial was interrupted before the planned 80 patients were enrolled.

CONCLUSION: Albeit underpowered, this study tends to indicate that thioctic acid may be beneficial in migraine prophylaxis. Before any firm conclusion can be drawn, however, a large multicenter trial is necessary.

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