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Petasites hybridus root (butterbur) is an effective preventive treatment for migraine

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Abstract

Objective: To evaluate the clinical efficacy of a standardized special root extract from the plant Petasites hybridus as a preventive therapy for migraine.

Methods: This is a three-arm, parallel-group, randomized trial comparing Petasites extract 75 mg bid, Petasites extract 50 mg bid, or placebo bid in 245 patients with migraine. Eligible patients met International Headache Society criteria for migraine, were ages 18 to 65, and had at least two to six attacks per month over the preceding 3 months. The main outcome measure was the decrease in migraine attack frequency per month calculated as percentage change from baseline over a 4-month treatment period.

Results: Over 4 months of treatment, in the per-protocol analysis, migraine attack frequency was reduced by 48% for Petasites extract 75 mg bid (p = 0.0012 vs placebo), 36% for Petasites extract 50 mg bid (p = 0.127 vs placebo), and 26% for the placebo group. The proportion of patients with a > or =50% reduction in attack frequency after 4 months was 68% for patients in the Petasites extract 75-mg arm and 49% for the placebo arm (p < 0.05). Results were also significant in favor of Petasites 75 mg at 1, 2, and 3 months based on this endpoint. The most frequently reported adverse reactions considered possibly related to treatment were mild gastrointestinal events, predominantly burping.

Conclusions: Petasites extract 75 mg bid is more effective than placebo and is well tolerated as a preventive therapy for migraine. Petasites 50 mg PO bid was not significantly more effective than placebo on the primary study endpoints.

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