Efficacy and Tolerability of a combination product with L-Tryptophan, Griffonia simplicifolia, Vitamin PP and Vitamin B6 in pediatric migraine prophylaxis: an open study

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The aim of this study was to evaluate the efficacy and tolerability of combination product with L-tryptophan, Griffonia simplicifolia, Vitamin PP and Vitamin B6 in prophylaxis therapy of pediatric migraine.

Fifthy outpatients (32 F, 18 M), mean age 10.7 years (SD 5.8), range 4-18 years, suffering from ICHD-2 migraine without aura were enrolled. The mean duration of disease was 2.9 (SD 1.6) years, range 1-4 years. At baseline the mean frequency of attacks was 7.6/month (SD 3.3), range 4-12; the mean number of drugs intaking for acute attacks was 6.6 tablets/month (SD 2.2).
During the six month evaluation period the combination product with L-tryptophan, griffonia simplicifolia, vitamin PP and vitamin B6 was administered (at dose 100 mg, 480 mg, 18 mg and 1 mg/die, respectively). All patients filled a headache-diary card during the evaluation.
The basal frequency of attack was 7,6 (SD 3.3) and 4,2 (SD 2.6), 3,6 (SD 2.8), 2,2 (SD2.6), after 1, 3 and 6 months respectively [$P < 0.01$; $P < 0.01$; $P < 0.01$]. The basal value of intaking drugs for acute attacks was 7,6 (SD 3.3) and 2,1 (SD 2.5), 1,9 (SD 1.5), 1,4 (SD 2.7) after 1, 3 and 6 months respectively [$P < 0.01$; $P < 0.01$; $P < 0.1$] (T-test analysis). The combination product with L-tryptophan, griffonia simplicifolia, vitamin PP and vitamin B6 was well tolerated (11 patients complained somnolence, diarrhea and gastralgia but none patient withdrew the study).
These data showed a good efficacy in reduction of frequency and intensity of headache attacks, a good tolerability and a very good reduction of drugs intaking for acute attacks.
Our study suggests that the combination L-tryptophan, griffonia simplicifolia, vitamin PP and vitamin B6 could be an alternative therapy for pediatric migraine prophylaxis.