Pharmacotherapy of attention-deficit hyperactivity disorder in children: the results of a multicenter double-blind placebo-controlled study of hopantetic acid

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AIM:

To assess the efficacy and safety of hopentetic acid (pantogam) compared to placebo in the treatment of attention deficit hyperactivity disorder (ADHD) in children, aged from 6 to 12 years, during 4 months in the prospective multicenter comparative double-blind placebo-controlled study in parallel groups.

MATERIAL AND METHODS:

One hundred patients enrolled in the safety assessment population were stratified into two equal pantogam and placebo groups. Eighty-nine patients who completed the study according to the protocol were included in the efficacy assessment group: 45 in the pantogam group and 44 in the placebo group. Pantogam was administered in tablets (250 mg) in the therapeutic dose 30 mg/kg of body mass, divided into 2 doses, during 4 months. Patient's state was assessed by the total score on ADHD-DSM-IV, CGI-S WFIRS-P, and results of the Toulouse-Piéron test for sustained attention.

RESULTS AND CONCLUSION:

There was a trend towards an increase in the percentage of patients with positive changes (a decrease in the total ADHD-DSM-IV by ≥25%) at the end of the 3rd and 4th month in the pantogam group (treatment response was 66.7 and 68.9%, respectively) compared to the placebo group (treatment response was 52.3 and 61.4%, respectively). A significant decrease in disease severity assessed by the CGI-S was noted in the pantogam group compared to the placebo group. After 4 months of treatment with pantogam, the severity of functional disturbances was reduced by 4 out of 6 WFIRS-P domains: Family, School and learning, Child's self-concept and Risky activities. Pantogam improved the measures of sustained attention (accuracy and speed) in the Toulouse-Piéron test. The drug used in mean daily dose 30 mg/kg during 4 months had a favorable safety profile which did not differ from that of placebo.