Agomelatine as a Treatment for Attention-Deficit/Hyperactivity Disorder in Children and Adolescents: A Double-Blind, Randomized Clinical Trial

Salardini Elaheh, Zeinoddini Atefeh, Kohi Asghar, Mohammadi Mohammad-Reza, Mohammadinejad Payam, Khiabany Mohammad, Shahriari Mona, and Akhondzadeh Shahin.


Objective:
Attention-deficit/hyperactivity disorder (ADHD) is a chronic neurodevelopmental disorder. Due to lack of response to the medication and significant side effects of the treatment with stimulants, alternative medications should be considered. The aim of this study is to evaluate efficacy of agomelatine in treatment of ADHD.

Methods:
Fifty-four outpatients, children 6–15 years old, with diagnosis of ADHD according to DSM-IV-TR diagnostic criteria participated in a 6-week, parallel, double-blind, randomized clinical trial. Fifty patients completed 6 weeks of treatment with either ritalin (methylphenidate hydrochloride [MPH]) (20 mg/day in participants below 30 kg and 30 mg/day in patients with weight ≥30 kg) or agomelatine (15 mg/day in patients with weight ≥30 kg and 25 mg/day in patients with weight ≥45 kg). Participants were assessed using Parent and Teacher ADHD Rating Scale-IV at baseline and at weeks 3 and 6.

Results:
General linear model repeated measures showed no significant differences between the two groups on Parent and Teacher Rating Scale scores (F = 1.13, df = 1.26, p = 0.305, and F = 0.95, df = 1.25, p = 0.353, respectively). Changes in Teacher and Parent ADHD Rating Scale scores from baseline to the study end were not significantly different between the agomelatine group (9.28 ± 8.72 and 24.12 ± 7.04, respectively) and the MPH group (6.64 ± 11.04 and 25.76 ± 7.82, respectively) (p = 0.46 and p = 0.44, respectively). There was a trend for less insomnia in the agomelatine group versus MPH-treated group (4% vs. 24%, p = 0.09).

Conclusions:
A treatment course of 6 weeks with agomelatine demonstrated a favorable safety and efficacy profile in children and adolescents with ADHD. Nonetheless, larger controlled studies with longer treatment periods are necessary.