MELATONIN FOR INSOMNIA IN CHILDREN WITH ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) ON STIMULANTS


INTRODUCTION

Objective: To test effectiveness of sublingual melatonin for children with ADHD on stimulants who were experiencing initial insomnia.

Attention-Deficit/Hyperactivity Disorder (ADHD) is a common neurological disorder affecting 5% of children worldwide. Stimulant medications used to manage symptoms may exacerbate the severity of existing initial insomnia. The use of pharmacological agents to promote sleep is common, but evidence regarding safety and effectiveness for pediatric use is lacking. In the absence of approved pharmacotherapy, melatonin may be particularly effective in children with ADHD to improve sleep onset latency (SOL).

METHODS

Multicenter, randomised, triple-blind, placebo-controlled series of N-of-1 trials with an embedded RCT.

If a two-week sleep hygiene phase did not improve sleep onset latency SOL, participants underwent three pairs of treatment/placebo periods (total 6 weeks)

Weight-based dosing:
• 3 mg sublingual melatonin for children < 40 kg
• 6 mg for those ≥ 40 kg.

Participants’ parents recorded daily measurements of SOL (primary outcome) in online sleep diaries.

RESULTS

Average SOL analysed as aggregated N-of-1 trials using Bayesian statistical modelling:
• Placebo- 50.7 (95% credible interval 42.7, 60.0) minutes
• Treatment- 32.2 (95% credible interval 27.5, 37.2) minutes
• [posterior probability 0.83, strong evidence that the difference was greater than 15 minutes]

On average, melatonin improved SOL by 18.5 minutes compared to placebo. A 15 minute difference is clinically significant

CONCLUSIONS

There was strong evidence that the difference in SOL between melatonin and placebo was greater than 15 minutes. Melatonin was effective in reducing SOL in children with ADHD on stimulants who were experiencing initial insomnia.