COMPARISON OF PARENTAL EXPECTATIONS AND CLINICAL CUTOFF FOR IMPROVEMENT IN SLEEP ONSET LATENCY IN CHILDREN WITH ADHD ON STIMULANTS


INTRODUCTION

Objective: To compare parent expectations for sleep onset latency (SOL) reduction with the clinical target of 30 minutes, in a trial of melatonin for insomnia in children with ADHD on stimulants.

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 SOL.

METHODS

Multi-centre, 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

![Figure 1. Comparison of the days clinical and parental SOL targets were met on melatonin and placebo, respectively. On melatonin, patients reached the clinical cut-off of 30 minutes a median of 0.60 of the days [IQR 0.37-0.83] and achieved the individual parental target a median of 0.71 of the days [IQR 0.53-0.89]. On placebo, the clinical cut-off was reached a median of 0.30 of the days [IQR 0.14-0.54] and patients achieved the individual parental target a median of 0.33 of the days [IQR 0.16-0.66].](image)

<table>
<thead>
<tr>
<th>Group</th>
<th>Median Sleep Hygiene SOL (minutes)</th>
<th>Parent expectation SOL reduction (minutes)</th>
<th>Parent target time to sleep (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical-Melatonin</td>
<td>75</td>
<td>31.4</td>
<td>36</td>
</tr>
<tr>
<td>Clinical-Placebo</td>
<td>53</td>
<td>25.7</td>
<td>30</td>
</tr>
<tr>
<td>Parental-Melatonin</td>
<td>105</td>
<td>91.2</td>
<td>45</td>
</tr>
<tr>
<td>Parental-Placebo</td>
<td>52</td>
<td>65.5</td>
<td>15</td>
</tr>
</tbody>
</table>

CONCLUSIONS

Though the majority of children had very long SOL, median parental SOL expectations and clinical target were similar (36 vs 30 minutes, respectively). Children with SOL >60 minutes had more difficulty reaching either clinical or parental targets. Parent SOL expectations could be used to inform clinical decisions about melatonin continuation when children with long SOL do not meet clinical SOL targets.