Melatonin in Youth: N-of-1 trials in a stimulant-treated ADHD Population (MYNAP): study protocol for a randomized controlled trial


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Abstract

Background
Attention-deficit/hyperactivity disorder (ADHD) is a common neurological disorder affecting 5% of children worldwide. A prevalent problem for children with ADHD is initial insomnia. The gold standard treatment to manage ADHD symptoms is stimulant medications, which may exacerbate the severity of existing initial insomnia. Currently, no gold standard treatment option exists for initial insomnia for these children. Melatonin, a hormone and a popular natural health product, is commonly provided to children by parents and recommended by healthcare providers, but high quality pediatric evidence is lacking.

Methods/design
This trial is a multicenter randomized triple-blind, placebo-controlled, parallel-group, randomized, controlled trial (RCT), in which each participant is offered an N-of-1 trial. An N-of-1 trial is a multiple-crossover, randomized, controlled trial conducted in a single individual. For the N-of-1 trial, each participant will undergo three pairs of treatment/placebo periods; each period is 1 week in length. Half the participants will have melatonin in the first period, the other half will start with placebo, and this will make up the parallel-group RCT. The primary outcome will be mean difference in sleep onset latency as measured by sleep diaries. A comparison of treatment effects yielded by the RCT data versus the aggregated N-of-1 trial data will also be assessed.

Discussion
This trial will provide rigorous evidence for the effectiveness of melatonin in children with ADHD on stimulants who experience initial insomnia. Further, this study will provide the first prospectively planned head-to-head comparison of RCT data with pooled data from a series of N-of-1 trials. Aggregated N-of-1 trials may be a powerful tool to produce high quality clinical trial evidence.

Trial registration numbers