

Sleep Assessment in Sleep Disorders



Background

Chronic insomnia disorder, characterized by difficulty initiating or maintaining sleep, is associated with poor health outcomes and reduced productivity¹. Pharmacological therapies are useful for patients with insomnia when access to treatments such as cognitive behavioral therapy is limited, or other treatments have proven ineffective. Zelira Therapeutics investigated the effectiveness of a cannabinoid-based medicine (ZTL-101) for chronic insomnia disorder in a randomized controlled trial².

Approach

Sleep quality and quantity measured as secondary outcomes in the trial using the following methods:

- Patient self-report from sleep diary captured from a 2-week baseline and 2-week treatment period,
- Actigraphy-based measures from data captured from a 2-week baseline and 2-week treatment period, and
- Polysomnography (PSG)-based measures captured on the 14th night of both baseline and treatment periods.

Outcome

Insomnia Severity Index (ISI) scores at the end of 2 weeks of ZTL-101 were significantly lower than scores following 2 weeks of placebo, suggesting that the treatment had a positive effect on insomnia symptoms. Statistically significant improvements in self-reported sleep diary and objective actigraphy-based measures of sleep quality and quantity were also documented, whereas PSG measures did not show a statistically significant change.

Clinical Study Design Impact

Outcome Measure Accuracy

Actigraphy-based, objective measures collected across multiple weeks increased sensitivity of sleep measures compared to a single night of PSG sleep measures for baseline and treatment periods in this study. Further, actigraphy measures of sleep were collected in a home environment in contrast to PSG measures made in a laboratory setting, which limits ecological validity, particularly in a condition like insomnia.

Potential Value Realized

Risk Reduction and Revenue Opportunities

Including objective measures of sleep quality and quantity reduced the risk of the trial results being inconclusive. It's likely that if the team had only included traditional measures of PSG and self-reported data, an open question may have remained as to whether the treatment increased objectively measured sleep time in a natural environment.

References

1. Daley, M. et al. Insomnia and its relationship to health-care utilization, work absenteeism, productivity and accidents. *Sleep Med* 10, 427-438 (2009).
2. Walsh, J. H. et al. Treating insomnia symptoms with medicinal cannabis: a randomized, crossover trial of the efficacy of a cannabinoid medicine compared with placebo. *Sleep* 44, (2021).