

Trial of Zolpidem for Sleep in Children With Autism

NCT05540574

Status	RECRUITING
Phase	Phase 2
Sponsor	Stanford University
Enrollment	26 participants

Key Eligibility Criteria

Inclusion (11)

- Participants will meet the following
- Outpatients between 8 and 17 years of age with only 12- 17 years of age at time of consent during year 1
- Diagnostic and Statistical Manual, 5th edition (DSM-5) criteria for Autism Spectrum Disorder (ASD) on the basis of clinical evaluation, confirmed with the Autism Diagnostic Interview-Revised (ADI-R) and the Autism Diagnostic Observation Schedule, 2nd Ed (ADOS-2) or the Childhood Autism Rating Scale, Second Edition (CARS-2)
- Males and females
- Availability of polysomnography (PSG) and/or actigraphy data
- ... and 6 more (see full listing online)

Exclusion (12)

- Participants will be excluded if one or more of the following is met
- active suicidal ideation or DSM-5 diagnosis of severe depression, substance use disorder, schizophrenia, schizoaffective disorder, or psychotic disorder
- unstable medical problems: migraine, asthma, seizure disorder, significant physical illness (e.g., anaphylaxis, serious liver, renal, or cardiac pathology) and hepatic insufficiency
- evidence of a metabolic, or infectious etiology for the participant's autism on the basis of medical history, neurologic history, and available tests for inborn errors of metabolism;
- pregnant or sexually active females not using a reliable method of contraception (urinary tests for pregnancy will be employed in this study)
- ... and 7 more (see full listing online)

Locations (1 total)

Stanford University, Stanford, California, United States