

Trial of Diphenhydramine for Sleep in Children With Autism

NCT05501678

Status	RECRUITING
Phase	Phase 2
Sponsor	Stanford University
Enrollment	26 participants

Key Eligibility Criteria

Inclusion (10)

- Participants will meet the following
 - Outpatients between 8 and 17 years of age at the time of consent
 - 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) or actigraphy data
- ... and 5 more (see full listing online)

Exclusion (11)

- Participants will be excluded if one or more of the following is met
 - active suicidal ideation or DSM-5 diagnosis of schizophrenia, schizoaffective disorder, or psychotic disorder
 - active medical problems: migraine, asthma, seizure disorder, significant physical illness (e.g., anaphylaxis, serious liver, renal, or cardiac pathology)
 - 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 and chromosomal analysis
 - pregnant or sexually active females not using a reliable method of contraception (urinary tests for pregnancy will be employed in this study)
- ... and 6 more (see full listing online)

Locations (1 total)

Stanford University, Stanford, California, United States

<https://clinicaltrials.gov/study/NCT05501678>

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