

A Study of Pitolisant in Patients With Prader-Willi Syndrome

NCT06366464

Status	RECRUITING
Phase	Phase 3
Sponsor	Harmony Biosciences Management, Inc.
Enrollment	134 participants

Key Eligibility Criteria

Inclusion (4)

- Genetically confirmed diagnosis of PWS
- Excessive daytime sleepiness
- Has a consistent parent/caregiver (preferably the same person throughout the study) who is willing and able to complete the required study assessments.
- In the opinion of the Investigator, the patient/parent(s)/caregiver(s)/legal guardian(s) are capable of understanding and complying with the requirements of the protocol and administration of oral study drug.

Exclusion (3)

- Has a diagnosis of sleep apnea (OSA, CSA) that is not adequately controlled
- Has a diagnosis of hypersomnia due to another sleep/medical disorder
- Participation in an interventional research study involving another investigational medication, device, or behavioral treatment within 30 days or 5 half-lives (whichever is longer) of the investigational medication prior to Screening

Locations (54 total)

Santa Monica Clinical Trials, Los Angeles, California, United States
Center of Excellence in Diabetes and Endocrinology, Sacramento, California, United States
Rady Children's Hospital - Scan Diego, San Diego, California, United States
... and 51 more locations