

Pediatric Down Syndrome Post-Approval Study

NCT06851338

Status	RECRUITING
Phase	Not Applicable
Sponsor	Inspire Medical Systems, Inc.
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (7)

- Patient has been diagnosed with Down syndrome;
- Patient is 13-18 years of age;
- Patient has been diagnosed with severe obstructive sleep apnea, with an AHI of ≥ 10 and ≥ 50 based on a recent (within 6 months of enrollment) qualified in-lab sleep study (PSG);
- Patient has documented failure of, or intolerance to, positive airway pressure therapies (such as CPAP or BiPAP) despite attempts to improve compliance;
- Patient is contraindicated for, or not effectively treated by, adenotonsillectomy;

... and 2 more (see full listing online)

Exclusion (9)

- Patient's recent PSG (within 6 months of enrollment) reports central + mixed apneas $\geq 25\%$ of the total apnea-hypopnea index (AHI);
- Patient has any anatomical finding that would compromise the performance of upper airway stimulation, such as the presence of complete concentric collapse of the soft palate;
- Patient has any condition or procedure that has compromised neurological control of the upper airway;
- Patient, or their parent/guardian, is unable or does not have the necessary assistance to operate the patient remote;
- Patient is pregnant or plans to become pregnant;

... and 4 more (see full listing online)

Locations (6 total)

Phoenix Children's Hospital, Phoenix, Arizona, United States
Children's Hospital Orange County, Orange, California, United States
University of South Florida Morsani College of Medicine, Tampa, Florida, United States
... and 3 more locations

<https://clinicaltrials.gov/study/NCT06851338>

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