

Self-Supporting Nasopharyngeal Airway (ssNPA) Treating Upper Airway Obstruction in Hypotonia

NCT05527652

Status	RECRUITING
Phase	Not Applicable
Sponsor	University of Michigan
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (5)

- Children with Hypotonic Upper Airway Obstruction (HUAO): This includes those who newly diagnosed with obstructive sleep apnea (OSA). These children will undergo overnight polysomnography to determine the presence of OSA (apnea-hypopnea index $[AHI] > 10$ or $AHI > 5$ with nocturnal hypoxemia defined as oxygen saturation by pulse oximetry $[SpO_2]$ nadir $\leq 75\%$).
- All subjects require the presence of at least one symptom of OSA (such as snoring 3 or more nights per week, daytime sleepiness, or hyperactive/inattentive behaviors)
- Post adenotonsillectomy or those with contraindications to tonsillectomy.
- Tonsil size 2+ or smaller.
- Parent/caregivers willing and able to provide informed consent and child willing and able to provide assent, where appropriate.

Exclusion (10)

- AHI ≥ 10 on polysomnogram (PSG) without hypoxemia or $AHI < 5$ with hypoxemia.
- Any medical reason why Self-Supporting Nasopharyngeal Airway (ssNPA) therapy may not be suitable
- Active Coronavirus (COVID) 19 infections
- End-tidal carbon dioxide (ETCO₂) or Transcutaneous carbon dioxide (TCO₂) values > 60 mmHg for $> 10\%$ of sleep time on PSG
- Psychiatric, medical, or social factors likely to invalidate assessments, make adherence with ssNPA highly unlikely or make local follow-up at 8 weeks unfeasible. Some psychiatric conditions may be provoked or exacerbated by OSA, and those most commonly implicated - Attention Deficit/Hyperactivity Disorder, Conduct Disorder, and Oppositional Defiant Disorder - will not be exclusions. However, more pervasive conditions such as severe autism will be excluded.

... and 5 more (see full listing online)

Locations (1 total)

The University of Michigan, Ann Arbor, Michigan, United States