Treatment of Obstructive Sleep Apnea With Personalized Surgery in Children With Down Syndrome (TOPS-DS)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 2 years to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Requirements to participate in study:

Child has a diagnosis of Down syndrome (Trisomy 21). Child has a diagnosis of moderate to severe OSA diagnosed by PSG (oAHI ≥ 5). Child age is 2.00 to 17.99 years of age. Caregiver can provide signed and dated consent and is 18 years of age or older at the time of consent.

Caregiver can speak, read, and write in English or Spanish. Caregiver is primary caretaker of the child. Child is not expecting their own child. Child is eligible for surgical treatment

Cannot participate in study if:

Child has history of previous tonsillectomy, tonsillotomy, or partial tonsillectomy.

Child has any contraindication to surgery (e.g. bleeding disorders). Child has significant cardiopulmonary comorbidity besides OSA requiring supplemental oxygen, subglottic or tracheal stenosis, tracheostomy dependence.

Caregiver is unwilling or unable to comply with study procedures. Child is or plans to have their own child.

Conditions & Interventions

Interventions:
PROCEDURE: DISE-Directed Surgery, PROCEDURE: Adenotonsillectomy
Conditions:
Obstructive Sleep Apnea, Down Syndrome

More Information

Description:
The overall objective of this randomized clinical trial is to test the effectiveness of a personalized approach to the surgical treatment of OSA in children with Down syndrome (DS).The estimated prevalence of obstructive sleep apnea (OSA) in children with DS ranges from 45-83%, compared to 1-6% in the general pediatric population. Untreated OSA in children has been associated with daytime sleepiness, cognitive or behavioral problems, and cardiovascular complications, all which are common in children with DS. Adenotonsillectomy (AT) is the first line treatment for OSA in children, however, most large studies of AT outcomes have excluded children with DS. Available evidence demonstrates that AT is far less effective in children with DS than in the general pediatric population, with 48 to 95% of children with DS having persistent OSA after AT. Medical treatments such as positive airway pressure (PAP) therapy are frequently inadequate or poorly tolerated in this population, so many children with DS and OSA remain untreated. Drug-induced sleep endoscopy (DISE) enables direct observation of the sites and patterns of obstruction during sedated sleep using a flexible endoscope passed through the nose into the pharynx. DISE was developed to guide surgical decisions in adult OSA, and in recent years has also been used to design personalized surgical interventions in children. Using this DISE Rating Scale, the investigators have demonstrated that children with DS are more prone to tongue base and supraglottic obstruction than non-DS children, suggesting the need for more personalized surgical treatments that are tailored to the common sources of obstruction in this population. Several small case series demonstrate that DISE-directed surgery can be effective in treating OSA in children with DS. However, because there have been few prospective studies and no randomized trials comparing different treatment options in this population, there remains uncertainty about whether such a personalized approach leads to superior outcomes compared to the first line AT. It is the investigators' hypothesis that personalized DISE-directed surgery that uses existing procedures to address specific fixed and dynamic anatomic features causing obstruction in each child with DS will be superior to the current first line approach of AT. This novel approach may improve OSA outcomes and reduce the burden of unnecessary AT or secondary surgery for persistent OSA after an ineffective AT.

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