Comparison of a Demand Oxygen Delivery

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 5 years to 17 years old
Healthy Volunteers: This study is also accepting healthy volunteers
Inclusion Criteria:

1. Age 5-17 years with or without Down Syndrome (DS).
2. Children with obstructive sleep apnea (OSA) and obstructive apnea hypopnea index (OAHI) 5-40 / hour: The rationale for selecting this range of OAHI is that a large number of children with DS with this range of OSA severity are untreated for months to years. It is important to understand the response to oxygen across the spectrum of disease severity. Notably, children with severe disease are left with few options (e.g., tracheostomy).
3. Absence of clinically significant hypoxia defined as oxygen saturation < 88% for 5 minutes or episodic desaturation to 60% as these levels would otherwise identify children eligible to routinely receive oxygen.

Exclusion Criteria:

1. Current CPAP use with documented compliance (> 4 hrs/ night; > 70% of nights).
2. Oxygen saturation < 90% at rest during wakefulness
3. Chronic daytime or nighttime use of supplemental oxygen.
4. Unable to participate in a Polysomnogram (PSG).
5. Enrolled or planning to enroll in another study that may conflict with protocol requirements or confound results in this trial.

Conditions & Interventions

Interventions:
DEVICE: Portable oxygen concentrator Inogen G5 model
Conditions:
Obstructive Apnea
Keywords:
Sleep Apnea, Down Syndrome, Continuous Positive Airway Pressure (CPAP)

More Information

Description:
Conducting a randomized control trial of oxygen in children with Down syndrome to treat moderate to severe obstructive sleep apnea. The aim of the study is to conduct a comparison between the 2 methods of oxygen delivery during sleep in 15 children from Cincinnati Children's Hospital and Children's Hospital of Los Angeles. 2 polysomnographies will be performed, one with continuous flow and the second with pulse flow.

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