Down Syndrome Obstructive Sleep Apnea

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 5 years to 18 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Ages 5.0 to 17.9 years at the time of screening
2. Children with OSA and obstructive apnea hypopnea index (OAHI) ≥5/hour.
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.
4. Favorable response to oxygen therapy (allowing randomization) will be defined as follows:
    1. Oxygen saturation nadir >92% and
    2. Decrease in obstructive index < 5 / hour or by > 50% from screening PSG
    3. Reaching an optimum oxygen flow which is defined as the flow that achieves the lowest level of AHI with maximum CO2 level less than 65 mmHg observed for 5 consecutive minutes and or an increase in CO2 by less than 15 points above baseline. The above criteria are observed while the patient spends a minimal of 30 minutes in the supine position and at least one cycle of rapid eye movement (REM) sleep.
    4. Oxygen flow required does not exceed 3.0 LPM and does not exceed a FiO2 > 40 %.
5. Willingness to comply with all study procedures and available for duration of study.
6. At baseline the participant attempts to perform the neuropsychological tests

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. Smoker in the child's bedroom.
5. Unrepaired congenital heart disease.
6. Moderate to severe pulmonary hypertension requiring treatment with oxygen and or pulmonary vasodilator.
7. Unable to participate in a PSG.
8. Individuals who develop alveolar hypoventilation with oxygen as previously defined.
9. Other severe chronic diseases determined by their provider as making them poor study candidates.
10. Enrolled or planning to enroll in another study that may conflict with protocol requirements or confound results in this trial.
11. Documented clinically significant untreated hypothyroidism
12. Children with adenotonsillar hypertrophy who are candidates for adenotonsillectomy and parents agree to the surgery.

Conditions & Interventions

Interventions:
DRUG: Oxygen
Conditions:
Down Syndrome, Obstructive Sleep Apnea

More Information

Description:
The purpose of this study is to assess whether oxygen supplementation during sleep improves working memory and other clinical and patient-reported outcomes among children who have Down Syndrome (DS) with moderate to severe Obstructive Sleep Apnea (OSA).

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