



Oxygen Therapy in Children and Adolescents with Down Syndrome and Obstructive Sleep Apnea

Down Syndrome and Sleep Apnea Study for Children 5 to 17 Years Old

Why are we doing this research?

We are conducting a research study, sometimes known as a clinical trial or clinical study, to show how 6 months of oxygen treatment while sleeping affects your sleep, quality of life, your breathing, your heart and if it makes you feel better. We also want to see if the oxygen helps decrease the severity of your obstructive sleep apnea (OSA).

Who can participate?

Children and teens 5 to 17.9 years old who are diagnosed with Down syndrome and who:

- Have been diagnosed with OSA
- Have not been successful with CPAP or unable to use it

What will happen in the study?

This study includes 4 to 5 visits over 7 months. Here are some of the things that will happen in this study:

Your child will be asked for:

- A Screening Visit
- An Eligibility confirmation
- An Informed consent
- Demographics
- A Medical History Review
- A Review of medications your child is taking

We are testing how oxygen therapy works. We will randomly assign participants into two groups. One group will receive oxygen therapy, and the other group will not. Both groups will receive a nasal strip to improve breathing and education about good sleep habits and about, healthy diet, and weight management. At the beginning of the study and again after 6 months, we will make measurements of your child's sleep, brain function, heart, and the quality of life.

You will be given a consent form that thoroughly explains all of the details of the study. A member of the study staff will review the consent form with you and will be sure that all of your questions are answered.

What are the good things that can happen from this research?

The benefit of participating in the study is that the parent/caregiver will know that the child's OSA could be treated with oxygen. Based on the information we get from this study, children who have OSA in the future may benefit from what is learned during this study.

What are the bad things that can happen from this research?

"We will discuss possible risks or discomforts with those interested in learning more about the study."

Will you/your child be paid to be in this research study?

Participants will receive up to \$735 for their time and effort.

Where can I find additional information?

For more information, please contact your closest recruiting site.

Sites And Contact Information

Recruiting Centers:

Cincinnati Children's
Hospital Medical Center
Cincinnati, Ohio, United States, 45229
Contact: dosastudy@cchmc.org

Children's Hospital of Philadelphia
Philadelphia, Pennsylvania, United States, 19104
Contact: dosastudy@chop.edu

Rainbow Babies and Children's Hospital,
University Hospitals Cleveland Medical Center
Cleveland, Ohio, United States, 44106

Data Coordinating Center:

Brigham and Women's Hospital
Boston, Massachusetts, United States, 02115
Contact: bwhdosasupport@bwh.harvard.edu

Contact: dosastudy@uhhospitals.org

University of Michigan,
Michigan Medicine
Ann Arbor, Michigan, United States, 48109
Contact: dosastudy@umich.edu

Children's Hospital of Los Angeles
Los Angeles, California, United States, 90027
Contact: dosastudy@chla.usc.edu

East Virginia Medical Center
Norfolk, Virginia, United States, 23507
Contact: dosastudy@evms.edu

Seattle Children's Hospital
Seattle, Washington, United States, 98105
Contact: dosastudy@seattlechildrens.org