

Down Syndrome and Sleep Apnea Study



for Children
and Teens 5
to 17 Years Old



Why are we doing this research?

Cincinnati Children's is conducting a research study to look at oxygen as a treatment of obstructive sleep apnea (OSA) in children with Down syndrome. The main reason for the study is to show how 6 months of oxygen treatment while sleeping affects the participants sleep, quality of life, breathing, heart and if it makes the participant feel better.

Who can participate?

Children 5 to 17 years old who are diagnosed with Down syndrome and who:

- Have been diagnosed with OSA
- Have had their tonsils and adenoids removed
- Have not been successful with CPAP or unable to use it

What will happen in this study?

The study involves 3 daytime visits and 2-3 overnight sleep studies at Cincinnati Children's during a 7 month period. Children in the study will be randomly placed in 1 of the following 2 groups:

- Oxygen therapy group: will be provided an oxygen machine, nasal strips, healthy sleep habits, and diet and weight management information
- Supportive care group: will be provided nasal strips, healthy sleep habits, and diet and weight management information.

Here's some of the things that will happen in this study:

- Heart examinations by ultrasound (echocardiography)
- Activity monitoring, which involves wearing a watch-like device for 7 days to measure sleep and activity. A sleep diary will also be completed.
- Monthly telephone calls with the study team
- Behavioral testing
- Parent questionnaires
- Blood pressure monitoring
- Body measurements

Will you be paid to be in this research study?

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

Who should I contact for more information?

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