



IS YOUR CHILD WITH DOWN SYNDROME HYPERACTIVE, INATTENTIVE, OR IMPULSIVE?

IF SO, YOU MAY BE INTERESTED IN THIS NEW RESEARCH STUDY:

PURPOSE:

We would like your help! We are interested in learning how guanfacine immediate release (GIR) acts in the bodies of children with Down syndrome. We are conducting a study called "Guanfacine for Hyperactivity in Children with Down Syndrome" (HYP01) to better understand the safest and most effective dose of GIR in children with Down syndrome to treat hyperactivity, inattention or impulsivity. Knowing the right dose of medicine for children is important to have the best outcome and the fewest side effects.

WHO CAN BE IN THE STUDY?

- Children with Down syndrome (DS) who are between the ages of 6 and 12 years old,
- who have non-mosaic DS,
- who have hyperactivity, inattention or impulsivity,
- and who meet other eligibility criteria to be in the study.

IS THERE ANY COST?

There are no additional costs for participating in this study

INTERESTED?

Contact name:

Contact title:

Site name:

Phone:

Email address:

WHAT'S INVOLVED?

- Once enrolled, your child will be in the study for approximately 10 weeks. We will ask you to come to the office on day 1, and at week 4 and week 8.
- We will ask you questions about your child's medical history, prescribed medicines, and demographics (e.g., age, ethnicity, race).
- This is a randomized placebo-controlled study, which means your child may be given either active study drug or a placebo.
- We will collect blood samples up to 3 times (at screening, week 4 and week 8 visits).
- We will perform an electrocardiogram (ECG) to assess your child's heart rhythm at screening, week 4 and week 8 visits (to do this we will attach small sticky pads to your child's chest, arms, and leg).
- You will complete questionnaires about your child's behavior and sleep and will complete a diary of when your child took their medication.
- We will call you weekly to see how your child is doing on the medication and discuss whether to increase the dose.



The Pediatric Trials Network (PTN – pediatrictrials.org) is a group of more than 100 research sites around the world that are working to find the safest and most effective doses of commonly used medicines for infants and children. Children aren't just little adults. Their bodies are growing and changing, meaning that medicines work differently in their bodies than they do in adults. The PTN works to make sure doctors and families have the information they need to give children the right dose: one that will get them well and keep them safe.

The study was made possible with support from the Eunice Kennedy Shriver National Institute of Child Health and Human Development.