Do I have to pay for my child to be in the study?

No. Your child will receive the study medication and all study-related care at no cost. You may also be reimbursed for travel and parking expenses.

Who runs this study?

The study sponsor is Supernus Pharmaceuticals, Inc., a company based in Rockville, Maryland. The study is being conducted in study clinics across the United States.

Some questions you should ask the study doctor:

- What is being studied?
- What are the possible side effects and risks?
- What will my child have to do?
- What tests and procedures are involved?

Getting in touch:

To learn more about the CHIME clinical research study, please contact:

chime
Childhood Impulsive Aggression & Molindone ER

This research study is called CHIME, which stands for Childhood Impulsive Aggression & Molindone ER. The study medication is being tested to see how safe it is and how well it works when given with other medications children may be taking.

ClinicalTrials.gov
Study Identifiers: NCT02618408/NCT02618434

If your child is being treated for ADHD,

but has trouble controlling anger…

Learn more about a clinical research study opportunity.

chime
Childhood Impulsive Aggression & Molindone ER

What is impulsive aggression?

All children occasionally get frustrated or show aggression, but children with impulsive aggression (IA) will also show:

- Unanticipated aggression due to frustration, annoyance, or other reasons
- Behavior that is unplanned
- Out of control emotional and physical displays lasting longer than expected

Examples of IA include arguing, cursing, yelling, threatening, throwing things, hair pulling, and hitting. The child is out of control and the aggression does not seem to have a reason.

What is the CHIME clinical research study?

IA intensifies the psychological, academic, emotional, and social problems that go along with attention deficit hyperactivity disorder (ADHD). This increases the risk of ongoing behavioral problems, encounters with the justice system, disciplinary problems at school, and sometimes substance abuse that frequently extends later into life.

Current medications for ADHD do not appear to relieve IA symptoms in some children, so doctors are conducting the CHIME clinical research study. This research study will determine whether a new study medication is safe and effective in helping reduce IA in children with ADHD.

Clinical research studies evaluate medications and medical devices on patient volunteers to make sure they are safe and effective prior to being released to the general public. The studies are carefully designed and conducted to make patient safety the priority, and the studies are overseen by regulating agencies such as the Food and Drug Administration (FDA).

What are the requirements to enroll in the CHIME study?

Your child may qualify for this research study if he or she:

- Is 6 to 12 years old
- Has been diagnosed with ADHD
- Is being treated with medication for ADHD
- Displays symptoms of IA
- Is able and willing to swallow pills
- Is able to attend clinic visits with a parent or caregiver

Additional requirements apply.

What will happen during the study?

Participants in the study will be divided into three groups (selected randomly by a computer). Two-thirds will take active study medication (one or more tablets, twice a day) and one-third will take a placebo. The placebo looks like the study medication, but contains no active ingredients. During the study, your child will continue to take his or her current ADHD medication in addition to the study medication.

The study requires seven clinic visits over approximately 12-13 weeks, which includes procedures such as physical exams, blood and urine samples, and electrocardiograms. You will also be given an electronic diary to record information every day about your child's IA experience (including IA behaviors) during the study.

Is it safe to participate in the study?

It is possible your child's IA will improve, but it is not guaranteed. Like with any standard clinical trial, there is a risk your child may not have a positive experience and side effects are also possible. Your child's health, however, is a high priority and will be monitored at all times.

Is participation voluntary?

If your child qualifies for the study and you agree to participate, you will sign an informed consent form stating that the details of the study have been explained to you. This is not a contract, and you may withdraw your child from the study for any reason at any time.