

About Bipolar Disorder

Bipolar disorder is a severe chronic mood disorder characterized by episodes of mania and depression. In the United States, in any given year, up to 4% of the population 18 years of age and older and 1.8% of children and teens are affected by this condition.

Bipolar disorder is characterized by at least one manic episode (a sustained period of an abnormally elevated mood, with intense energy or extreme and exaggerated behavior) that may be preceded or followed by a hypomanic or depressive episode (bipolar depression). Compared to manic and hypomanic episodes, bipolar depression is more common and usually lasts longer.

Although emotional and unruly behavior are a relatively normal part of childhood, there are a few signs and symptoms that may indicate a depressive episode associated with bipolar disorder (bipolar depression). Some may include:

- Depressed mood
- Loss of interest or pleasure
- Suicidal thoughts or behavior
- Difficulty falling asleep
- Loss of energy
- Difficulty concentrating



Principle Investigator: Bradley Grant, D.O.
IRB00281389

TO LEARN MORE, CONTACT

Kennedy Krieger Institute
Phone #: 443-923-3850

The Balance Study is a research study evaluating the safety and effectiveness of an investigational drug in children and teens who have been diagnosed with Bipolar Depression.



The Balance Study is evaluating an investigational drug for children and teens who have been struggling with symptoms of bipolar depression.

What the Balance Study involve?

The Balance Study will last for approximately 12 weeks. During your/your child's participation in the study, you will visit a study center within a short distance of your home for various tests, assessments, and checkups.

Before participating in the study, participants will complete a screening period to see if they are eligible for the study. If they are eligible, participants will proceed to the 6-week study-treatment period where the investigational drug capsule or placebo will be taken by mouth at the same time daily. After the study-treatment period has been completed, there will be a follow-up period where the study staff will check in on your/your child's well-being.

The research team will be able to explain more about what the Balance Study will involve, and it is up to you or your child to decide if you want to take part. Participation in this study is voluntary. Whether or not you decide to participate in this study will not affect your current or future relationships with your doctors. If you decide to participate, you are free to withdraw at any time without affecting those relationships.



The Balance Study

Bipolar depression can change the way a child or teen interacts with the world around them.

If you or your child have bipolar depression we are inviting you to take part in the Balance Study for children and teens, aged 10 to 17 years of age, who have been struggling with bipolar depression.

The Balance Study will enroll about 380 children and teens with bipolar depression at participating study centers throughout North America and Europe. The study team will be able to further discuss whether you or your child are eligible for the study.

The purpose of this study is to evaluate an investigational drug for bipolar depression in children and teens.

Is there a cost to participate?

Participants who qualify to take part in the study may receive compensation for travel for study related visits.

There is no cost to participate in the Balance Study. If you decide to take part:

- You will receive study-related care throughout the study from a team of experienced doctors.
- All study-related visits, tests, and investigational drug will be provided at no cost to you or your child.

Who can take part in the study?

You or your child may be eligible to join the Balance study if you or they:

- Are 10 to 17 years old
- Have a diagnosis of bipolar disorder
- Are currently experiencing an episode of depression:
 - Symptoms of bipolar depression include depressed mood, loss of interest or pleasure, suicidal thoughts or behavior, difficulty falling asleep, loss of energy, difficulty concentrating