



401 and 402 Studies

Patient and Family Information

ITI-007 Bipolar
Depression
Program

Thank you for your interest in the 401 and 402 Studies

This brochure contains information that may help you decide whether you would like to take part in the clinical research studies, 401 **or** 402.

The 401 and 402 Studies are clinical research studies looking at whether an investigational medication can improve the symptoms of bipolar depression (bipolar I or bipolar II disorder). It also aims to look at how safe the investigational medication is and whether it impacts the quality of life and wellbeing of people with bipolar depression.

In total, approximately 1098 adults in the United States with bipolar depression are planned to take part in the studies.





What is a clinical research study?

A clinical research study is a medical study designed to answer questions about the safety and efficacy (how well it works) of potential new treatments (called investigational medications). Without clinical research studies, no new medications would be developed and few medical advances would be made.

Choosing to take part in a clinical research study is an important personal decision for you, and your family. You might find it helpful to talk to the staff at your treatment center or your regular doctor about the study.

About the 401 and 402 Studies

The 401 Study will look at the investigational medication when it is taken on its own. The 402 Study will look at the investigational medication when it is taken by patients who are already taking a mood stabilizer, specifically lithium or valproate.

In these studies, participants will either receive the investigational medication, or placebo, which looks the same as the investigational medication but contains no actual medication. Participants of these studies will be placed into one of three treatment groups at random (like flipping a coin). Two groups will receive the investigational medication at different doses, and one group will receive placebo. There is a two in three chance of receiving the investigational medication.

Why are these studies being done?

Right now, there are few available treatments that are approved for bipolar depression. There is a need for a treatment that works, has fewer side effects, and can be used alone or with a mood stabilizer. The investigational medication in these studies is taken as a capsule, once per day in the evening. More than 600 people have already taken the investigational medication in other clinical research studies, and it has been generally well tolerated. It is hoped that the information gathered during these studies will help us to improve treatment for people with bipolar depression in the future.



What will happen during the 401 and 402 Studies?

The studies will last up to 12 weeks and will require nine visits to the study center.

There are three parts to the studies (periods):

Screening Period

(2 weeks, but could last up to 4 weeks)

The study doctor will ask you some questions and perform some tests to see if one of the studies is right for you.

Treatment Period

(6 weeks)

If one of the studies (401 or 402 Study) is suitable for you, you will be placed into one of the three treatment groups and will begin taking your study medication (investigational medication or placebo).

Your study medication will come in a card containing two strips of capsules, and you should take two capsules (one from each strip) **once per day in the evening for 6 weeks.**

If you are in the 402 Study, you will already be taking a mood stabilizer and should keep taking it in addition to the study medication.

During this treatment period, you will need to visit the study center weekly for tests.

Safety Follow-Up Period

(2 weeks)

You will have a final study visit to check your health, approximately 2 weeks after your last dose of study medication.

What kind of health assessments will I have during the 401 and 402 Study visits?

During the study visits, participants will have certain health assessments and procedures, which may include:

- a physical examination of your body
- height and weight measurements
- blood pressure, heart rate, breathing rate, and body temperature
- blood tests, using blood taken from a vein in your arm
- urine tests
- an electrocardiogram (ECG), which is a painless test to check the electrical activity and rhythm of your heart
- various questionnaires (you may have to complete some of these electronically) and interviews.





Who can take part in the 401 and 402 Studies?

You may be able to take part in the 401 or 402 Study if you:

- are between 18 and 65 years of age (inclusive)
- have been diagnosed with bipolar I or bipolar II disorder
- are currently having a major depressive episode that started at least 2 weeks ago, but no more than 6 months ago
- have previously had at least one bipolar manic episode or mixed episode (if you have bipolar I disorder) or hypomanic episode (if you have bipolar II disorder).

What else do you need to consider?

- Taking part in the 401 and 402 Studies is entirely voluntary. You will be able to stop taking part at any time.
- You will need to take your study medications exactly as instructed by the study team.
- You must agree to attend all study visits and study assessments.
- There will be no charge for the study medications, or for any of the health assessments done as part of the study.
- All study participants will receive a high standard of care, and will be monitored closely throughout the study by the study team.
- Whether you receive the investigational medication or placebo, taking part in one of these studies may help us better understand which treatments work best for people with bipolar depression.

To learn more about taking part in the 401 or 402 Study, please contact the study team. We look forward to hearing from you.



585.241.9670