The RECOVERY Study

Frequently Asked Questions

If you are dealing with stress, anxiety, or insomnia due to a traumatic event that occurred in your adult life (age 18 or older) and within the past 9 years, you may qualify for the RECOVERY Study. The study is exploring the effect of an investigational medicine on trauma-related PTSD symptoms when taken nightly before bed for 12 weeks.

1. What is the purpose of a clinical trial?

Before a drug can be approved by the US Food and Drug Administration (FDA) and then be prescribed by your doctor, it first must be tested through a series of clinical studies to make sure it is safe and it works. These studies are conducted at research sites throughout the country and must conform to strict rules set forth by the FDA. These rules help protect the rights and safety of those who volunteer to take part in clinical trials.

2. Who is conducting the RECOVERY Study?

Tonix Pharmaceuticals is sponsoring this study and has carefully selected qualified, licensed physicians and medical specialists to carry out the study procedures.

3. Do I need a previous diagnosis of PTSD to join the study?

No. At your first visit, the study doctor will evaluate you to see if you meet the criteria for a diagnosis of PTSD. A previous diagnosis is not required.

4. How many people will participate in the RECOVERY Study?

About 250 people are expected to participate at approximately 30 study locations throughout the United States.

5. Will I have to pay for anything if I participate?

If you choose to participate, you will receive all study-related care at no cost to you. You can also get reimbursed for travel-related expenses. Health insurance is not required to participate.

6. How will I know if I qualify for the study?

About a week or two prior to starting the study, you will come in for what is known as a Screening Visit. At this visit you will have a full physical exam which will include vital signs, labwork and an EKG. The doctor will also obtain a complete medical history and will confirm your diagnosis of PTSD by an interview with you. In the interview, you will also discuss with a staff member how your symptoms of PTSD are impacting your life to ensure that you qualify for the study.

7. How long does the study last? What happens at the visits?

If you qualify for the study, you will take the study medication for 12 weeks. During this period, you will visit the doctor's office 4 times – once to begin the treatment period, and then at week 4, week 8, and week 12.

At these visits, you and the study team will try to determine if there has been any change in your symptoms or overall health. You will discuss with the doctor and the staff how well you are sleeping, how your symptoms of post-traumatic stress may have changed and whether or not your daily life has been impacted. You will be compensated for your time and travel to attend these visits.

8. Does everyone in the study receive the investigational drug?

No, as part of the study you will be randomly assigned (by chance) to receive either the investigational drug, or a "placebo" (an identical-looking pill, but with no active medication). You will have a 50% chance of receiving the investigational drug or the placebo, and neither you nor your study doctor will know which one you are receiving.

9. Why is it done that way? Why can't I just get the study medication?

In order to determine whether the active medication works, we need to compare it to something else in order to maintain scientific standards. This is why we use placebo, to help "control" the trial. Using this comparator helps keep everyone honest and prevents people from just saying "it works" when in fact the medication might not work.

10. What if I join the study and later decide I do not want to participate anymore?

As with all clinical studies, your participation is completely voluntary. You may leave the study at any time without any effect on your future medical care. However, if you leave the study early, you cannot enter the extension study.

11. I am interested in possibly moving forward. What is the next step?

Participating in a clinical trial is a tremendous gesture that lets you be part of the process that helps advance the science and treatment of medical problems. You get to have a voice and be part of the development of a medication that may help many others with PTSD in the future.

If this sounds like something you'd like to help with, please contact your local study center, and they will work with you to schedule a convenient time for your initial visit.

RECOVERY STUDY