[redacted]

About the [redacted] Study

A guide for care partners of study participants

Welcome

Thank you for considering participation in the [redacted] Study with your loved one. We are grateful for your interest in research on schizophrenia.

This guide includes helpful information about the study and clinical research participation. If you have any questions or concerns, please do not hesitate to reach out to the study team.

What is the [redacted] Study?

The purpose of the [redacted] Study is to further research a study drug called [redacted] in people with schizophrenia. The goal of the study is to better understand how well [redacted] may prevent relapse in participants with schizophrenia.

Participation in this study will last up to 47 weeks (about 12 months) and includes the following periods:

- **Screening period (up to 2 weeks):** Includes at least one visit. During this period, interested individuals will be admitted to an inpatient facility and will take health tests and assessments to determine if the study is a good match.
- **Dosing adjustment period (5 weeks):** Includes at least five visits. During this period, participants will begin taking a [redacted] capsule (a study pill) twice daily at a few different dose levels. Participants will taper off of their current schizophrenia medication(s) over the course of the first week.
  - Participants may remain at an inpatient facility for up to three more weeks during this period until they meet the necessary discharge criteria, at the discretion of the study doctor.
- **Dosing stabilization period (12 weeks):** Includes at least six visits and six phone calls. During this period, participants will take one stable dose level of [redacted] twice daily.
- **Treatment period (26 weeks):** Includes at least nine visits and 17 phone calls. During this period, participants will take [redacted] or a placebo twice daily.
  - The placebo is a pill that looks just like [redacted] but contains no medication. The use of a placebo will help researchers learn accurate information about [redacted] by providing something to compare it to.

What is the [redacted] Study?

- **Follow-up period (2 weeks):** Includes at least one visit. Participants will stop taking the study pills and attend a study visit so that the study team can check on their health.
  - The study team will closely monitor the participant for a change in or worsening of symptoms during this time.

If your loved one chooses to join the study, they will be given a visit guide that explains what will happen at each study visit.

Your loved one will receive the study drug, study-related medical exams, and study-related laboratory tests at no cost. Support for study-related travel costs may be available.

Notes/questions

What is expected?

While your loved one is in the study, they must:

- Agree to follow the study rules
- Be willing to discontinue their current schizophrenia medications (this will be done slowly and with careful monitoring)
- Adhere with at-home study requirements, such as taking the study pills twice a day
- Not join any other clinical research studies
- Give correct information about their medical history and current medical condition
- Tell their study doctor about any health problems they have during the study
- Not take any other medications unless the study doctor has approved them ahead of time. This includes prescriptions and over-the-counter drugs (including vitamins, herbs, and other kinds of therapies).
  - The study doctor may check the blood of your loved one to detect the use of medications that are not approved for use during the study.
- Agree not to become pregnant, breastfeed a baby, or donate an egg or eggs during the study (for individuals of childbearing potential)

Participation in this study is completely up to your loved one. If enrolled, they may choose to stop their participation at any time for any reason.

Your role in the [redacted] Study

A support system for people with schizophrenia is important, especially during their participation in a clinical research study.

Your role is to help your loved one take part in the visits and tests required by the study and to help provide information on how they are doing and how the study drug may be affecting them.

You can help your loved one with study participation by:

- Talking with the study doctor or staff about how your loved one is doing, especially if there are any changes to their health
- Helping your loved one get to and from study appointments
- Assist with your loved one's daily study requirements, such as taking the study pills twice a day
- Knowing that your loved one has the right to leave the study at any time for any reason

Care partners may experience feelings of exhaustion known as care partner burnout, which can make it more difficult to care for others. Some ways to avoid care partner burnout include:

- Getting at least seven hours of sleep
- Paying attention to eating and exercise habits
- Planning meals ahead of time
- Taking time for yourself

We understand that joining a clinical research study is a big commitment. If you or your loved one have any questions or concerns, please talk to your loved one's doctor or contact the study team listed here:

Study doctor: _____

Study coordinator: _____

Address: _____

Phone: _____

Email: _____

To learn more about clinical research for schizophrenia, visit: [redacted]ClinicalTrials.com

What you should know about clinical research studies

Clinical research studies, also called clinical trials, are done to answer specific questions about how medicines work. You and your loved one should feel fully informed about what to expect from joining a clinical research study.

Researchers use clinical research studies to:

- Learn about the safety and effects of investigational medicines, which have not yet been approved and are being tested
- Help find new ways of using certain medications
- Answer specific health questions

Participation in any clinical research study is entirely up to the volunteers. The study team will inform you and your loved one of the potential risks and benefits of participation, as well as possible side effects. To make a decision, talk to your loved one's health care providers about any questions you may have.

All clinical research studies are:

- Made to protect the rights, safety, and well-being of participants
- Done according to strict scientific and ethical principles
- Reviewed and approved by an institutional review board (IRB) or ethics committee (EC)

Notes/questions

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Notes/questions

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[redacted]

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Thank you
for considering a clinical study

The importance of representation in research: Research has shown that certain diseases and treatments may affect people differently based on several factors, including social determinants of health.[1] For this reason, it is important that people from all backgrounds be involved in medical research.

1. Social Determinants of Health. my.clevelandclinic.org/health/articles/social-determinants-of-health Accessed June 24, 2025.