What is an investigational study medication?

An investigational study medication is a medication that has not been approved by any regulatory health authorities. Study medications are only available to people who participate in research studies.

Who participates in a research study?

Research participants are people who have a condition that is being studied and volunteer to be in the study. Study doctors/staff determine who is eligible to participate. Being in a research study is not the same as receiving medical care, which is done to treat a specific condition.

Study doctors, who are often experts in the condition or disease being studied, will closely track the health of study participants. This means that study participants typically get a high level of care and attention during a research study.

What is Informed Consent?

Informed Consent occurs before you agree to participate in a research study. It allows you to learn everything about a research study and why it is being done. A study team member will go over the informed consent form, which contains all of the study details, with you and answer any questions you may have.

After your questions have been answered and if you wish to participate in the study, you will sign the informed consent form which says that you:

- Agree to volunteer in the study
- · Understand what you will be asked to do in the study
- Understand any risks and potential study-related side effects
- Understand that you can stop the study at any time and for any reason

If you do not understand something about the study, you may continue asking questions. However, you must read and sign the informed consent form before you can participate in the study.

To learn more, please contact:





Depression research wants to bring light back to your view.

Learn about the **VENTURA-2** research study for adults and elderly people with major depressive disorder (MDD) who experience a loss of interest or pleasure. This study is evaluating an investigational medication that is taken with your current antidepressant medication

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Around the world, depression affects hundreds of millions of people. If you have depression and are taking antidepressant medication but still have symptoms, the VENTURA-2 study may be an option for you.

The purpose of this study is to see if a study medication is effective and safe when it is taken with your current antidepressant medication. The study medication is investigational, which means that it is not approved to treat depression. It is only available to people with depression who agree to be in this study.

This study will help doctors and researchers learn if the study medication is effective and safe and could one day be available to people with depression.

You may be able to participate in this study if you:

- Are 18 to 74 years old
- · Have been diagnosed with depression
- Are experiencing depressive symptoms despite currently taking antidepressant medication

What will happen during the VENTURA-2 study?

If you agree to participate in the study, you will be randomly assigned (like the flip of a coin) to take either the study medication or placebo, which looks like the study medication but contains no active medication. There is an equal chance of you receiving the study medication or placebo.

During your study participation, you will be asked to:

- Take the study medication or placebo once a day for 42 days (6 weeks)
- Continue to take your antidepressant medication
- Attend a total of 10 visits, 6 in-person and 4 over the phone

You will be in the study for up to 12 weeks (3 months). This includes screening for eligibility, study dosing, and may include a follow-up.

If you finish the study, you may also have the option to participate in a long-term study where all participants will be given the study medication.

There is no cost to participate in this study. All study-required visits, tests, and study medication will be provided to you. You may also be reimbursed for study-required travel costs.

What are the benefits and risks related to the VENTURA-2 study?

You may or may not benefit from participating in the study. However, your study participation may help people with depression in the future.

You may experience one or more side effects during this study. Before you begin the study, the study team will go over any known study-related risks and side effects with you.

You will be closely monitored for any study-related side effects or changes in your health while you are in this study.

Do I have to participate in the VENTURA-2 study?

No, it is your choice to participate in this study. Even if you agree to participate, you are free to stop being in the study at any time and for any reason.

Your decision about participating in this study will not affect your regular medical care. You may choose to talk with your doctor, family, and friends about whether this study could be right for you.



The image depicted contains models and is being used for illustrative purposes only.

Frequently Asked Questions

What is a research study?

A research study helps us to learn more about an investigational study medication. It allows us to learn things about an investigational study medication like how safe it is, how it makes people feel, and what the best dose may be.

What we find out from research studies helps doctors to decide if an investigational study medication could one day be made available to others outside of the study.