

Exploring the changing tide in managing depression



The **KOASTAL** program is investigating the effects of a once-daily study medicine intended to work in a new way to treat adults living with depression (also called Major Depressive Disorder or MDD). This study medicine is being evaluated to see whether it can improve the symptoms of depression

Ask your doctor if KOASTAL is right for you or someone you love, at **www.KOASTALstudy.com** or connect with us at **xxx-xxx**

KOASTAL is evaluating a study medicine that is currently not approved for sale in any country

KOASTAL is evaluating a once-daily study medicine that was created to work in a new way on specific pathways in your brain that affect key symptoms of depression, including the feelings of having less interest or pleasure in the things you used to enjoy. This is a new approach that works differently than SSRIs or SNRIs

You may be able to participate if you:

- are 18–65 years old
- have been told by a doctor that you have depression
- have had symptoms of depression for 1–12 months
- are not pregnant or breast feeding
- can give consent and can follow study instructions

The study doctors will explain all the requirements to you. Being in a clinical study is voluntary and you can leave the study at any time. There are study centers across the United States and Canada, and you can remain connected with your own doctor throughout the study. During KOASTAL, if you qualify, you will receive all study-related care from a dedicated medical team at no cost. Reimbursement for study-related expenses may be available to you

Ask your doctor if the KOASTAL study is right for you or a loved one living with depression

Learn more at www.KOASTALstudy.com or call us at xxx-xxx-xxxx



SSRI, selective serotonin reuptake inhibitor; SNRI, serotonin and norepinephrine reuptake inhibitor

What to Expect in the KOASTAL Study

Participating in KOASTAL has 3 main parts:



Part 1: Screening

Timing: about 28 days

You will visit the study doctor's office, where the study doctor will talk to you and run tests to determine whether you can be in the study. The study doctor will use questionnaires to understand your symptoms of depression. You may need to make further office visits during this period, as determined by your study team





Part 2: Treatment period

Timing: 6 weeks

You will be randomly assigned to 1 of 2 treatment groups (study medicine or placebo pill). You will not know which type of pill you are receiving. Your doctor will explain how to record each pill you take, so no doses are missed. You will visit the clinic 5 times and the study doctors will ask about your symptoms of depression using the same questionnaires and note any side effects. You may stop treatment at any time and for any reason

After 6 weeks of treatment, you can choose to leave the study, or be considered for the long-term study



Part 3: Long-term study

Timing: about a year

If you wish to join the long-term study, a doctor will first check that you are eligible

There is no placebo pill – everyone will take a once-daily study medicine to help doctors understand the effects of treatment over time. You will visit the study doctor's office 6 times and have 4 calls with the study doctor to check your symptoms using the same questionnaires and note any side effects

The most common antidepressants prescribed for depression include selective SSRIs and SNRIs. However, these medications do not manage depression successfully in all people



In one study, only about 3 of 10 people with depression experienced relief from all their symptoms when using these medications as their first treatment





Current antidepressants do not fully treat anhedonia (feelings of having less interest or pleasure in the things you used to enjoy), which occurs in up to 7 of 10 people with depression

We understand that participating in a study is a big decision. Talk with your family, doctors, or others who suffer from depression

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