

FREQUENTLY ASKED QUESTIONS

What is a clinical study?

Through clinical research, scientists and doctors can determine whether a new medical strategy, drug, or device is safe and effective for people. New treatments are not discovered without clinical research studies, which rely on study participants like you to evaluate their safety and effectiveness. Participation is voluntary, and study participants may withdraw from the study at any time.

What is an investigational medication?

An investigational medication also referred to as the study drug, is not yet approved for sale by any government health agency or authority. Clinical research studies (or trials) are used to test the safety and efficacy of an investigational medication.

What are the stages of development for a new medication?

Clinical trials are divided into phases, or stages, to thoroughly determine if a new medication is both safe and effective for use by the public. Typically, study drugs must pass through three phases of development: Phase 1, Phase 2, and Phase 3. The ADEPT-4 study is a Phase 3 study, which focuses on learning more about the use of the study drug, KarXT, as a treatment for psychosis associated with Alzheimer's disease.

How are my rights and safety protected as a participant during the ADEPT-4 study?

Your rights, well-being, and safety are of the utmost importance to the study staff during and after the study. Study staff will explain all aspects of the study to you and answer any questions that you may have. All clinical studies must follow strict guidelines on how participants are treated. These guidelines have undergone an ethical review and have been approved by those boards.



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A Clinical Research Study for Psychosis
Associated with Alzheimer's Disease



Alzheimer's Disease Psychosis Treatment Program



**DO YOU OR
SOMEONE YOU KNOW
STRUGGLE WITH
ALZHEIMER'S DISEASE
PSYCHOSIS?**

Learn more about this study opportunity!

What is Psychosis Associated with Alzheimer's Disease?

Psychosis associated with Alzheimer's disease (AD) often presents as delusions, paranoia, or hallucinations, and can become more prevalent as the disease worsens. These include delusions of persecution, infidelity, abandonment, misidentification delusions or the belief that loved ones close to them who have passed are still living. While diagnosis of Alzheimer's disease often focuses on cognitive deficits, the behavioral symptoms of psychosis and agitation often are the most troublesome for caregivers and lead to poor quality of life for patients.



WHY PARTICIPATE?

By participating in the ADEPT-4 study, you as the participant will:

- Play a role in the advancement of Alzheimer's disease with psychosis treatment
- Contribute to the data collected during this study that may help doctors learn more about KarXT and your disease
- Receive care from a local doctor at no cost to you or your study partner/caregiver

Thank you for your consideration in enrollment. By participating in this clinical study, you help doctors learn more about potential treatments for psychosis in Alzheimer's disease. You may even help others diagnosed with this disease, and potentially receive a possible new treatment option to help manage your symptoms. During the study, the participant will receive care and attention from a local doctor and study staff.

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WHAT TO EXPECT FROM THE ADEPT-4 STUDY?

Screening Period

To take part in this study, the participant will need to be evaluated to determine eligibility. It may take up to 30 days to evaluate a potential participant's eligibility for the study.

Study Treatment Period

Participants will be asked to take part in a 14-week treatment period where they will receive either KarXT or Placebo. Dosing is flexible and can change based on how well the participant tolerates the study drug and how well the study drug is working.

Follow-up Period

Once the participant stops taking the study drug, a follow-up visit will be performed to see how the participant is doing. The follow-up visit will occur four weeks after the last study visit.

Extension Period

Participants who complete the 14-week study may be eligible for a one-year, long-term Open-Label Extension (OLE) safety study.

ABOUT THE STUDY

What is the ADEPT-4 clinical study?

ADEPT-4 is a 14-week clinical study that will evaluate the safety and efficacy of KarXT, an oral medication, for the treatment of psychosis associated with Alzheimer's disease. The purpose of this study is to evaluate if the study drug, KarXT, may help in the treatment of psychosis in people with Alzheimer's disease compared to placebo (a substance that looks like KarXT but does not contain any active drug).

How can I participate in the study?

You may be eligible to participate if you:

- Are between the ages of 55 and 90
- Have mild to severe Alzheimer's disease with moderate to severe psychosis
- Have a history of psychotic symptoms for at least 2 months prior to screening
- Have a study partner/caregiver that will be able to attend all visits, report on the participant's status, oversee medication and treatment, and participate in some written study assessments

Clinical study eligibility requirements will apply, and only a qualified healthcare professional can determine if you or your study partner/caregiver is eligible to participate in the study.

How can I learn more about the study medication and this study?



Please visit

BMSClinicalTrials.com/ADEPT4 or visit
www.ClinicalTrials.gov, NCT#: NCT06585787

