

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ADEPT-5 STUDY

ADEPT-5 study

1. Study Information

Name of the study	A study to evaluate safety and efficacy of KarXT + KarX-EC as a treatment for psychosis associated with Alzheimer's disease
Study sponsor	Bristol-Myers Squibb
Disease	Psychosis associated with Alzheimer's Disease dementia
Phase	Phase III

2. Information about the drug that will be tested in the study

Name of drugs	KarXT + KarX-EC KarXT is the main investigational medicine that combines two agents: xanomeline (a drug that stimulates certain brain receptors important for cognition and behaviour) and trospium (a compound that helps reduce side effects outside the brain). KarX-EC is an enteric-coated formulation of xanomeline, meaning the xanomeline is coated to be released in the intestine rather than the stomach, which can improve tolerability and the delivery profile.
Administration	Oral administration (capsules)
Is the drug already on the market for another medical condition?	KarXT is approved in the US and China for the treatment of schizophrenia in adults.
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • An oral administration of KarXT + KarX-EC • An oral administration of placebo (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested with no active therapeutic effect). Neither the participant nor their doctor will know if the person is receiving the investigational drug or the placebo.

3. Information about participating in the trial

What are the researchers trying to find out?	• The purpose of the study is to evaluate the safety and efficacy of KarXT + KarX-EC for the treatment of psychosis associated with Alzheimer's disease dementia.
How long will the treatment last?	• 14 weeks
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their memory, hallucination, delusion, agitation and psychosis • Complete some laboratory tests to evaluate the emergent adverse events (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • Do physical examination and an electrocardiogram (ECG), which is a test that records the electrical activity of the heart. Further information on the number of visits can be obtained from the study team.

4. Who can participate in this study?

Who can participate in the study?	To take part in the study, participants must: • Be 55 to 90 years old • Have a biomarker confirmed diagnosis of Alzheimer's disease, in accordance with the 2024 Alzheimer's Association criteria • Have results of brain scans (MRI, CT) consistent with the clinical diagnosis of Alzheimer's disease • History of psychotic symptoms (according to the International Psychogeriatric Association [IPA] criteria) during the past two months.
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Who cannot participate in the study?	Exclusion criteria include: • Psychotic symptoms that are primarily attributable to a condition other than Alzheimer's disease-causing dementia (e.g., schizophrenia, schizoaffective disorder, delusional disorder, or mood disorder with psychotic features) • History of major depressive episode with psychotic features during the last 12 months • A disease that may interfere with the safety or study assessments (e.g., pulmonary, hepatic, renal, hematologic, gastrointestinal, endocrine, immunologic, dermatologic, neurologic, or oncologic disease). The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study.
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5. Where and when will the study be conducted?	
European country involved in the trial	• UK
Estimated start date of recruitment	June 2026

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT06947941	EUCT Number	2025-521057-16
Study contact information	Clinical.Trials@bms.com		
Link to full text	https://clinicaltrials.gov/study/NCT06947941		
Study's website	https://www.bmsclinicaltrials.com/content/studyconnect/us/en/clinical-trials/NCT06947941.html		

- ✓ The information contained in this document is based on information available on public registries (e.g., clinicaltrials.gov website) in August 2026.
- ✓ This document has been reviewed by a member of the European Dementia Carers Working Group.
- ✓ This document has been reviewed by the pharmaceutical company running this trial.