Alzheimer Europe

Making dementia a priority:
changing perceptions, practice and policy.

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ADEPT-4 STUDY

Alzheimer Europe • R.C.S. LUXEMBOURG F2773 • 5 Heienhaff, L-1736 Senningerberg
Tel. +352 29 79 70 • Fax +352 29 79 72 • info@alzheimer-europe.org • www.alzheimer-europe.org

ADEPT-4 study

1. Study Information	
Name of the study	A study to evaluate KarXT as a treatment for psychosis associated with Alzheimer's disease
Study sponsor	Bristol Myers Squibb
Disease	Psychosis associated with Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	KarXT (combines xanomeline with trospium chloride)
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: • Capsules of KarXT (specified dose on specified days) • Capsules 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 in people who have mild to severe Alzheimer's disease with moderate to severe psychosis related to Alzheimer's disease.
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 (MMSE, NPI-C, CGI-S, CMAI, ADAS-Cog). • To complete some laboratory and biological tests to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study). Further information on the procedures, tests and 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 between 55 and 90 years old • Have a biomarker confirmed diagnosis of Alzheimer's disease, according to the National Institute on Aging - Alzheimer's Association Guidelines for All-cause Dementia and Alzheimer's Disease • Have results of brain scans taken during or subsequent to the onset of dementia • Have a study partner who has a sufficient contact with the participant and willing to participate in study procedures throughout the study duration • History of psychotic symptoms (according to the International Psychogeriatric Association [IPA] criteria) during the past two months.
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 • History of bipolar disorder, schizophrenia or schizoaffective disorder. The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study.

5. Where and when will the study be conducted?	
European countries involved in the trial (active)	• Belgium • Bulgaria • Croatia • France • Germany • Greece • Hungary • Israel • Italy • Poland • Portugal • Romania • Serbia • Slovakia • Spain • Turkey
Estimated start date of recruitment	April 2025

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT06585787	**EUCT Number**	2024-516363-92-00
Study contact information	Clinical.Trials@bms.com		
Link to full text	https://clinicaltrials.gov/study/NCT06585787 https://euclinicaltrials.eu/ctis-public/view/2024-516363-92-00		
Study's website	https://www.bmsclinicaltrials.com/content/studyconnect/us/en/clinical-trials/NCT06585787.html		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) in April 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.