Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ADAGIO 2 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

ADAGIO 2 study

1. Study Information	
Name of the study	A phase 3 study to evaluate the safety and efficacy of KarXT + KarX-EC for the treatment of agitation associated with Alzheimer's disease
Study sponsor	Bristol-Myers Squibb
Disease	Agitation associated with Alzheimer's disease
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 this study is to evaluate the efficacy and safety of KarXT + KarX-EC in people with agitation 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 agitation and aggression • 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 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 confirmed diagnosis of Alzheimer's disease, in accordance with the 2024 Alzheimer's Association criteria • Have a score between 5 and 22 in the MMSE test (a test about your thinking skills) • Have a study partner who has a sufficient contact with the participant (10 hours/week), is willing to participate in study procedures throughout the study duration. • History of agitation.

Who cannot participate in the study?	Exclusion criteria include: • Agitation symptoms that are primarily attributable to a condition other than the Alzheimer's disease causing dementia • History of bipolar disorder, schizophrenia or schizoaffective disorder • History of (or at high risk for) urinary retention, gastric retention, or narrow-angle glaucoma • Risk of suicidal behaviour. 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)	• Czechia • France • Israel • Italy • Poland • UK
European countries that will be involved in the trial (planned)	• Germany • Hungary • Ukraine
Estimated start date of recruitment	October 2025

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT07011745	**EU CT Number**	2025-520612-34-00
Study contact information	Clinical.Trials@bms.com		
Link to full text	https://clinicaltrials.gov/study/NCT07011745 https://euclinicaltrials.eu/ctis-public/view/2025-520612-34-00		
Study's website	https://www.bmsclinicaltrials.com/us/en/clinical-trials/NCT07011745?id=NCT07011745		

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