



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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

TRAILBLAZER-ALZ 5 STUDY

TRAILBLAZER-ALZ 5 study

1. Study Information	
Name of the study	A Study of Donanemab (LY3002813) in participants with early symptomatic Alzheimer's disease
Study sponsor	Eli Lilly and Company
Disease	Early Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	Donanemab
Administration	The drug will be administered via an intravenous infusion (an injection into the vein).
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	<p>Participants will be selected by chance to receive one of the following options:</p> <ul style="list-style-type: none">• An intravenous infusion of donanemab• An intravenous infusion 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). <p>Neither the participant nor their doctor will know if the person is receiving the investigational drug or the placebo.</p>

3. Information about participating in the trial	
What are the researchers trying to find out?	<ul style="list-style-type: none">• The purpose of the study is to evaluate the safety and efficacy of donanemab in people with early symptomatic Alzheimer's disease (prodromal and mild dementia due to Alzheimer's disease) with the presence of brain tau pathology.
How long will the treatment last?	<ul style="list-style-type: none">• The study duration including screening and follow-up is up to 93 weeks.

<p>What your involvement will entail?</p>	<ul style="list-style-type: none"> • During the study, participants will be asked to complete a test that will assess their cognition (mental ability/understanding) and activities of daily living (this test is called Integrated Alzheimer's Disease Rating Scale (iADRS)) • Complete other tests that will assess their cognition, memory, behaviour and activities of daily living (i.e. tests like ADAS-Cog, ADCS-iADL, CDR-SB, MMSE) • Complete some laboratory tests to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • During the study, participants will have to undergo a brain scan (MRI, PET). <p>Further information on the number of visits can be obtained from the study team.</p>
--	--

<p>4. Who can participate in this study?</p>	
<p>Who can participate in the study?</p>	<p>To take part in the study, participants must:</p> <ul style="list-style-type: none"> • Be 60 to 85 years old • Have a gradual and progressive change in memory function reported by the participant or study partner for ≥ 6 months • Have a score between 20-28 points in the MMSE test (a test about a range of everyday mental skills). This would suggest that the person has an impairment that is at a very mild stage • Have evidence of abnormal accumulation of tau in their brain (as per results of brain scans) • Have a study partner who has a sufficient contact with the participant (at least 10 hours per week), is willing to

	<p>participate in study procedures throughout the study duration</p> <ul style="list-style-type: none">• If the person is taking symptomatic treatment medications for Alzheimer’s disease and other medications that may impact cognition, the dosing regimen must have been stable within the past 30 days.
Who cannot participate in the study?	<p>Exclusion criteria include:</p> <ul style="list-style-type: none">• Any evidence of a neurological or neurodegenerative condition other than Alzheimer’s disease that may affect cognition or the ability to complete the study, such as other dementias, serious infection of the brain, Parkinson's disease, multiple concussions, or epilepsy• A disease or medical condition that may interfere with the study assessments and will make the participant unsuitable for participation in or completion of the trial procedures (i.e. cardiovascular, hepatic, renal, gastroenterologic, respiratory, endocrinologic, neurologic (other than AD), psychiatric, immunologic, or hematologic diseases• History of cancer within the last 5 years, except some cancers with low risk of recurrence or spread• Contradictions to brain scans (MRI, PET) <p>The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study.</p>

5. Where and when will the study be conducted?	
European countries involved in the trial	<ul style="list-style-type: none"> • Poland • Spain • UK
Estimated start date of recruitment	April 2024

6. Information for your doctor			
Eu CT Number:	2025-522340-40-00	Clinicaltrials.gov identifier	NCT05508789
Study contact information	LillyTrials@Lilly.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05508789 https://euclinicaltrials.eu/ctis-public/view/2025-522340-40-00		

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