Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

TRAILBLAZER-ALZ 6 STUDY

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TRAILBLAZER-ALZ 6 study

1. Study Information	
Name of the study	A study of different Donanemab (LY3002813) dosing regimens in adults with early 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?	Participants will be selected by chance to receive one dose of Donanemab (between 4 doses). Participants will receive placebo at certain intervals to preserve the blind (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested with no active therapeutic effect).

3. Information about participating in the trial	
What are the researchers trying to find out?	• The purpose of the study is to investigate the effect of different doses of Donanemab on the frequency and severity of ARIA-E (a type of side effect caused by amyloid-modifying therapies) in people with early symptomatic Alzheimer's disease (prodromal and mild dementia due to Alzheimer's disease).
How long will the treatment last?	• The study will last approximately 91 weeks and include up to 26 visits.
What your involvement will entail?	• During the study, participants will have to undergo brain scan (MRI, PET) to evaluate the side effects and the amyloid level in the brain • Complete some laboratory tests (i.e. blood tests).

4. Who can participate in this study?	
Who can participate in the study?	To take part in the study, participants must: • 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 amyloid in their brain (as per results of brain scans) .
Who cannot participate in the study?	Exclusion criteria include: • Any evidence of a neurological or neurodegenerative condition other than Alzheimer's disease that may affect cognition or 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 • Presence or history of malignant neoplams within the last 5 years • A life expectancy of < 24 months • Participants must not have contraindication to MRI or PET scans.

	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 country that involved in the trial (active)	• UK
European country that will be involved in the trial (planned)	• Italy
Estimated start date of recruitment	April 2023

6. Information for your doctor			
Eu trial Number:	2022-502268-18-00	**Clinicaltrials. gov identifier**	NCT05738486
Study contact information	ClinicalTrials.gov@lilly.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05738486		

✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on May 2023.