Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

TRAILBLAZER-ALZ 2 STUDY

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TRAILBLAZER-ALZ 2 study

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

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 of the following options: • An intravenous infusion of Donanemab • An intravenous infusion of placebo (inactive substance identical in appearance to the drug being tested). 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, tolerability and efficacy of Donanemab in people with early symptomatic Alzheimer's disease.
How long will the treatment last?	• Around 1.5 year.
What your involvement will entail?	• During the study, participants will have to undergo brain scan (MRI, PET) to see if they have amyloid pathology in their brain • Complete a memory test (MMSE) to assess cognitive function

	• Complete a test that will assess memory, orientation, judgment and problem solving, personal care and community affairs (this is a test called CDR) • Participants will also need to complete some other tests to evaluate their cognition, behaviour, function and quality of life, activities of daily living (e.g. ADAS-Cog, ADCS-iADL). 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 60 to 85 years old • Have a gradual and progressive change in memory function for the past 6 months • Have a score between 20 and 28 points in the MMSE test (a test about your memory). This would suggest that the person has an impairment in their memory that is at a very mild stage • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration.
Who cannot participate in the study?	Exclusion criteria include: • Contraindication to PET imaging and MRI procedures • A current treatment with immunoglobulin G (IgG) therapy (people with immunodeficiency diseases involving poor IgG antibody (found in blood plasma) often benefit from a medical treatment called immunoglobulin G therapy.

	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 • Germany • Netherlands • Poland • UK
European country that will be involved in the trial (planned)	• France
Estimated start date of recruitment	October 2020

6. Information for your doctor			
EudraCT Number:	2020-000077-25	**Clinicaltrials.gov identifier**	NCT04437511
Study contact information	Clinicaltrials.gov@lilly.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT04437511		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on July 2021.
- ✓ This document has been reviewed by the pharmaceutical company running this trial.
- ✓ This document has been reviewed by a member of the European Working Group of People with Dementia.