Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

AHEAD 3-45 STUDY

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AHEAD 3-45 study

1. Study Information	
Name of the study	A study to evaluate efficacy and safety of treatment with Lecanemab in participants with preclinical Alzheimer's disease and elevated amyloid and also in participants with early preclinical Alzheimer's disease and intermediate amyloid
Study sponsor	Eisai
Disease	At risk of developing Alzheimer's disease Early Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	Lecanemab (also named BAN2401)
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 injection of Lecanemab, 5mg/kg every two weeks through 8 weeks, then 10 mg/kg every two weeks through 96 weeks and 10 mg/kg every four weeks through 216 weeks • An intravenous injection of placebo every two weeks through 96 weeks then every four weeks through 216 weeks (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested with no active therapeutic effect) • An intravenous injection of Lecanemab, 5mg/kg every four weeks through 8 weeks, then 10 mg/kg every four weeks through 216 weeks • An intravenous injection of placebo every four weeks through 96 weeks.

	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 Lecanemab in people with preclinical Alzheimer's disease and elevated amyloid (A45 Trial) and in people with early preclinical Alzheimer's disease and intermediate amyloid (A3 Trial)
How long will the treatment last?	• Around 4 years
What your involvement will entail?	• During the study, participants will be asked to complete some questionnaires to evaluate their cognition, behaviour, function and activities of daily living (e.g. PACC5, CFI, MMSE) • Complete a test that will assess memory, orientation, judgment and problem solving, personal care and community affairs (this is a test called CDR-SB) • All participants will be asked to undertake brain scans (PET) and those that opt in will have lumbar punctures (CSF) to see changes in biomarkers in the brain 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 55 to 80 years old • Participants who have between 55 and 64 years old must have one of the following risk factors: - First degree relative (a parent, brother or sister) diagnosed with dementia onset before 75 years old - Known to possess at least 1 apolipoprotein E4 variant (APOE4) allele, or

	- Known to have elevated brain amyloid according to previous PET or cerebrospinal fluid (CSF) tests • Have a score of 0 in the Clinical Dementia Rating-Global Score (CDR) and a score above 17 in the MMSE test (a test about your memory). This would suggest that the person has no impairment in its memory • Have a score above 6 in the WMS-R LM II test (a logic memory subtest) to measure the verbal episodic memory • Have evidence of abnormal accumulation of amyloid in their brain (PET scan) • Have a study partner who has a sufficient contact with the participant and is willing to participate in study procedures throughout the study duration.
Who cannot participate in the study?	Exclusion criteria include: • A pregnancy or lactation for female participants • History of a stroke, transient ischemic attack or seizures • A disease or conditions that may interfere with the safety, tolerability and/or study assessments, or put the participant at special risk (e.g. psychiatric symptoms, auto-immune disease, inflammatory neurological disorders) • Contraindication to PET brain scans • Known to be HIV positive • Drug or alcohol abuse or dependence • Participation in other clinical studies involving active immunization, unless it can be confirmed that the participant only received placebo. 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 involved in the trial	• Spain • UK
Estimated start date of recruitment	2021

6. Information for your doctor			
EudraCT Number:	2020-004244-28	**Clinicaltrials.gov identifier**	NCT04468659
Study contact information	esi_medinfo@eisai.com ahead-participate@usc.edu		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT04468659		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on January 2022.
- ✓ 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.