Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ENVISION STUDY

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ENVISION study

1. Study Information	
Name of the study	A study to verify the clinical benefit of Aducanumab in participants with early Alzheimer's disease
Study sponsor	Biogen
Disease	Early Alzheimer's disease
Phase	Phase III/IV

2. Information about the drug that will be tested in the study	
Name of drug	Aducanumab
Administration	The drug will be administered via an intravenous infusion (an injection into the vein), monthly (once every four weeks).
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 Aducanumab (up to 10 milligrams per kilograms (mg/kg)) • An intravenous injection 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 the study is to verify the Clinical Benefit of monthly doses of Aducanumab in slowing cognitive and functional impairment in people with early Alzheimer's disease.
How long will the treatment last?	• 2 years
What your involvement will entail?	• During the study, participants will be asked to complete a test that will assess memory, orientation, judgment and problem

	solving, personal care and community affairs (this is a test called CDR-SB) • Complete other tests that will assess their cognition, daily function, memory, and behaviour (i.e. tests like iADRS, ADCS-ADL-MCI, ADAS-Cog, MMSE, NPI-10) • Participants will have to undergo brain scan (PET). 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 history of subjective memory decline with gradual onset and slow progression over the 6 months before screening, confirmed by study partner • Have a study partner who has a sufficient contact with the participant (at least 10 hours/week in person or by phone), provides the necessary information about the participant's memory, behaviour and functioning • Have a score between 22-30 points in the MMSE test (a test about a range of everyday mental skills), a score of 0.5 or 1 on the Clinical Dementia Rating-Global Score (CDR-GS) and a score of 85 or lower in the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS). This would suggest that the person has an mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease according to National Institute on Aging and Alzheimer's Association (NIA-AA) criteria • Consent to apolipoprotein E (ApoE) genotyping

	• Have confirmed amyloid beta pathology by cerebrospinal fluid (CSF) or amyloid PET • Be in good health as determined by the Investigator based on medical history and screening assessments (apart from a clinical diagnosis of early Alzheimer's disease).
Who cannot participate in the study?	Exclusion criteria include: • Any evidence of a condition other than Alzheimer's disease that may affect cognition (e.g. other type of dementia, other neurodegenerative disease or infections with neurological involvement) • 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. delirium, psychosis, psychiatric disorder, stroke) • History of severe allergic or anaphylactic reactions or of hypersensitivity to any of the inactive ingredients in the drug product • Participation in any study with purported disease-modifying effect in Alzheimer's disease within 12 months • Current use or previous use of medications with a purported disease-modifying effect in Alzheimer's disease, outside of investigational studies • Prior exposure to aducanumab either commercially or by participation in a previous study with aducanumab. 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	• Belgium • Finland • France • Germany • Italy • Poland • Spain • Sweden • UK
Estimated start date of recruitment	December 2022

6. Information for your doctor			
EudraCT Number:	2022-001671-14	**Clinicaltrials.gov identifier**	NCT05310071
Study contact information	clinicaltrials@biogen.com		
Link to full text	https://classic.clinicaltrials.gov/ct2/show/NCT05310071		

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

✓ The pharmaceutical company running this trial has reviewed this document.