Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

EXPLAIN-AD STUDY

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EXPLAIN-AD study

1. Study Information	
Name of the study	Study of the efficacy and safety of various anti-inflammatory agents in participants with mild cognitive impairment or mild Alzheimer's disease
Study sponsor	Novartis Pharmaceuticals
Disease	Mild cognitive impairment or mild Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	Several anti-inflammatory agents will be tested. The first anti-inflammatory treatment used in this study is called Canakinumab (also named ACZ885).
Administration	Canakinumab will be administered via a subcutaneous injection (an injection under the skin).
Is the drug already on the market for another medical condition?	Yes - Arthritis
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • A subcutaneous injection of Canakinumab • A subcutaneous 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 evaluate the safety, tolerability and efficacy of anti-inflammatory agents in people with mild

	cognitive impairment or mild Alzheimer's disease with evidence of peripheral inflammation.
How long will the treatment last?	• A treatment period of 20 weeks (around 5 months) • After the 20-week period, study participant will be eligible to enter a follow-up period of 28 days.
What your involvement will entail?	• During the study, participants will be asked to complete a test that will assess their cognitive domain, in particular memory, executive function, attention and verbal fluency (this is a test called NTB) • To complete some laboratory/biological tests (i.e. blood tests, ECG) to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • To complete other tests that will assess their neuropsychiatric symptoms, activities of daily living and memory (i.e. tests like NPI, eCog, MMSE) • Participants will be asked to undertake brain scans (PET) 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 45 to 90 years old • Have a diagnosis of probable mild cognitive impairment due to Alzheimer's disease or a diagnosis of mild Alzheimer's disease according to the National Institute on Aging/Alzheimer's Association core clinical criteria

	• Have a score of between 20 and 30 in the MMSE test questionnaire test (a test about your memory). This would suggest that the person has an impairment in their memory that is at a mild stage • Have evidence of abnormal accumulation of amyloid and tau in the brain, determined through CSF examination (lumbar puncture) • 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: • A disease or conditions that may interfere with the safety, tolerability and/or study assessments (e.g., non-Alzheimer dementia, Huntington's disease, Parkinson's disease, stroke, schizophrenia, bipolar disorder, active major depression, multiple sclerosis) • Diagnosis of vascular dementia prior to screening • Previous treatment with amyloid vaccines or intravenous immunoglobulins meant to treat Alzheimer's disease. 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	• Finland • Iceland • UK
Estimated start date of recruitment	October 2021

6. Information for your doctor			
EudraCT Number:	2020-003966-38	**Clinicaltrials.gov identifier**	NCT04795466
Study contact information	novartis.email@novartis.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT04795466		

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