Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ACI-35-1802 STUDY

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ACI-35-1802 study

1. Study Information	
Name of the study	A study to evaluate the safety, tolerability and immunogenicity of Tau targeted vaccines in participants with early Alzheimer's disease
Study sponsor	AC Immune SA
Disease	Early Alzheimer's disease
Phase	Phase Ib/IIa

2. Information about the drug that will be tested in the study	
Name of drug	ACI-35.030 or JACI-35.054 or placebo
Administration	The active vaccine or placebo will be administered via injections.
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: • Injection of ACI-35.030 (low dose) • Injection of ACI-35.030 (medium dose) • Injection of ACI-35.030 (high dose) • Injection of JACI-35.054 • Injection 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 immunogenicity of different doses, regimens and combinations of Tau targeted vaccines in participants with early Alzheimer's disease.

How long will the treatment last?	• Around 12 months.
What your involvement will entail?	During the study, participants will have to • Complete some laboratory/biological tests (i.e., blood and cerebrospinal fluid samples, urinalysis, also including notably brain MRI, ECG, blood pressure, heart rate) to evaluate the emergent adverse events (unfavourable signs, symptoms or diseases temporally associated with the use of the drugs tested in the study) • Complete different study assessments that will notably evaluate levels of memory, orientation, judgment and problem solving, personal care and community affairs • Participants will also need to complete some other questionnaires to evaluate their cognition, behaviour and function (e.g. RBANS, NPI). Further and more detailed information on the number of visits and on the list of study assessments 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 notably: • Be 50 to 75 years old • Have a diagnosis of mild cognitive impairment due to Alzheimer's disease or mild to Alzheimer's disease according to the National Institute on Aging/Alzheimer's Association core clinical criteria • Have a score of 0.5 to 1 in the Clinical Dementia Rating-Global Score (CDR) and a score of 22 or above 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 very mild stage.

	• If the person is taking approved symptomatic medication for dementia (i.e. donepezil, rivastigmine, galantamine or memantine) the dosing regimen must have been stable for at least 3 months prior to the baseline visit • Be post-menopausal for at least one year or permanently sterilized for female participants • 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: • Participation in other clinical studies involving active immunization, unless it can be confirmed that the participant only received placebo • Participation in previous clinical trials for neurological disorders using any passive immunization within the past 12 months prior to screening or using small molecule drug within the past 3 months prior to screening • A disease that may interfere with the safety, tolerability and/or study assessments, or put the participant at special risk (e.g. auto-immune disease, inflammatory neurological disorders) • Drug or alcohol abuse or dependence • History of a stroke, transient ischemic attack or seizures • History of cancer within the past 5 years • A pregnancy or breast-feeding for female participants • Positive HIV test or Active hepatitis B and/or C.

	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?	
Countries involved in the trial	• Finland • Netherlands • Sweden • UK
Start date of recruitment	July 2019

6. Information for your doctor			
EudraCT Number:	2018-004573-27	**Clinicaltrials.gov identifier**	NCT04445831
Study contact information	clinicaltrials@acimmune.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT04445831		

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