Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ACI-24-1801 STUDY

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ACI-24-1801 study

1. Study Information	
Name of the study	A study comparing the safety and clinical effects of different formulations of a new vaccine, ACI-24 with placebo in patients with mild Alzheimer's disease
Study sponsor	AC Immune SA
Disease	Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	ACI-24
Administration	The drug will be administered via an intramuscular injection (an injection into the muscle).
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 intramuscular injection of ACI-24 • An intramuscular injection of placebo (a 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 immune response (reaction of the body) of the new vaccine ACI-24 in people with mild 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 some laboratory tests to evaluate the side effects (it refers to

	unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • Participants will have to undergo brain scan (PET, MRI) and CSF examination (spinal tap) to see if they have amyloid pathology in their brain • Complete a test that will assess their memory, orientation, judgment and problem solving, personal care and community affairs (this is a test called CDR) • During the study, participants will be asked to complete other tests that will assess their memory, functioning, behaviour, quality of life and other health-related questionnaires (i.e. tests or scales like MMSE, ADAS-Cog…) 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 50 to 85 years old • Meet the clinical criteria for probable Alzheimer's dementia of the National Institute on Aging/Alzheimer's Association (NIAAA) • Have evidence of abnormal accumulation of amyloid in their brain (as per results of PET scan) • Have a score between 20-28 points in the MMSE test (a test about a range of everyday mental skills). This would suggest that the person has an impairment that is at a mild stage • If the person is taking acetylcholinesterase inhibitor as an approved anti-dementia medication (i.e. donepezil,

	rivastigmine or galantamine) the dosing regimen must have been stable for at least 3 months prior to the screening visit • Be willing to have at least a study partner who has a sufficient contact with the participant, is willing to accompany the participant to all study visits, provides the necessary information about the participant's memory, behaviour and functioning • Females must be surgically sterile (e.g. have undergone surgical operation, be post-menopausal, or use adequate contraception) • Be lucid, clear and oriented (i.e. awareness of person, knowledge of place, time/date and event) • Be willing to consent and comply with all study schedules.
Who cannot participate in the study?	Exclusion criteria include: • Results showing pathology such as severe vascular encephalopathy or vascular dementia • History of a major psychiatric disorder or medical condition that may interfere with the safety or study assessments (e.g. Parkinson's disease, uncontrolled epilepsy, uncontrolled hypertension) • History of neurological disorders including meningoencephalitis or hemorrhagic stroke • Suicidal thoughts in the past six months, or suicidal behaviour in the past 12 months • Alcohol or drug abuse or dependence • Abnormal laboratory results (including anemia, liver disorders) • History of cancer within the past 5 years • Have any contraindication to brain scans (due to having prostheses, implants, a pacemaker or claustrophobia)

	• Diagnosis of infectious diseases (i.e. hepatitis B, C) or autoimmune disease (i.e. Rheumatoid arthritis, lupus, multiple sclerosis) or human immunodeficiency virus (HIV) • A pregnancy or breast-feeding for female participants • Treatment with anticoagulants. 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 country/site involved in the trial (active)	• Finland • Sweden • UK
European countries/sites that will be involved in the trial (planned)	• Poland
Estimated start date of recruitment	Aug 2018

6. Information for your doctor	
EudraCT Number:	2018-000445-39
Study contact information	clinicaltrials@acimmune.com
Link to full text	https://www.clinicaltrialsregister.eu/ctr-search/trial/2018-000445-39/FI

- ✓ The information contained in this document is based on information available on public registries (e.g. EU Clinical Trials Register website) on June 2019.
- ✓ 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.