Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ABvac40 STUDY

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ABvac40 study

1. Study Information	
Name of the study	Safety and immunogenicity of repeated doses of ABvac40 in patients with amnestic mild cognitive impairment or very mild Alzheimer's disease
Study sponsor	Araclon Biotech S.L.
Disease	Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	ABvac40
Administration	The drug will be administered via a subcutaneous injection (an injection under the skin). The first five injections will be administered monthly and the sixth at week 42.
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: • A subcutaneous injection of ABvac40 • A subcutaneous 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 of the first active vaccine targeting the C-terminal end of the Aβ40 peptide in people with amnestic mild cognitive impairment or very mild Alzheimer's disease.

How long will the treatment last?	• 42 weeks
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 be asked to do some blood tests to investigate the immune response. 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 both inclusive • Have a study partner who has a sufficient contact with the participant, is willing to accompany the participant to all study visits and sign the informed consent form • Have a score between 24-30 points in the MMSE test (a test about a range of everyday mental skills), 0.5 in the Clinical Dementia Rating-Global Score (CDR-GS) and RBANS Score on DMI of 85 or lower. This would suggest that the person has an impairment that is at a very mild stage • Have results of brain scans (MRI) consistent with the clinical diagnosis of an amnestic mild cognitive impairment or very mild Alzheimer's disease • If the person is taking treatment for Alzheimer's disease, the dosing regimen must have been stable within the 2 past months.
Who cannot participate in the study?	Exclusion criteria include:

	• Any allergies to components of the vaccine or allergy to fish or shellfish • Diagnosis of infectious diseases (i.e. hepatitis B, C) • Diagnosis or history of autoimmune disease (i.e. Rheumatoid arthritis, lupus, multiple sclerosis) or human immunodeficiency virus (HIV) • Diagnosis of kidney and/or liver disease • History of asthma within the past 6 months or currently on regular treatment • History of cancer within the past 5 years • Abnormal laboratory results (including anemia, serum B12 abnormality or thyroid function abnormality) • History of any neurological disorders, a major psychiatric disorder or medical condition that may interfere with the safety or study assessments or could be the cause of the dementia or the cognitive impairment • Suicidal thoughts in the past six months, or suicidal behaviour in the past five years • Treatment with anticoagulants • Have participated in a recent clinical study within the last month or within the past 12 months in the case of trials evaluating the effect of a drug on the progression of Alzheimer's disease • Any alcohol or drug abuse • Have any contraindication to brain MRI scans (due to having prostheses, implants, a pacemaker or claustrophobia) • A pregnancy or breast-feeding for female participants. 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	• France • Italy • Spain • Sweden
Start date of recruitment	December 2017

6. Information for your doctor			
EudraCT Number:	2016-004352-30	**Clinicaltrials.gov identifier**	NCT03461276
Study contact information	info@araclon.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT03461276		

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