Alzheimer Europe

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CLINICAL TRIALS WATCH

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ABATE STUDY

Alzheimer Europe • R.C.S. LUXEMBOURG F2773 • 5 Heienhaff, L-1736 Senningerberg
Tel. +352 29 79 70 • Fax +352 29 79 72 • info@alzheimer-europe.org • www.alzheimer-europe.org

ABATE study

1. Study Information	
Name of the study	A study to assess the effects of ACI-24.060 in Alzheimer's disease and in Down syndrome
Study sponsor	AC Immune SA
Disease	Alzheimer's disease
Phase	Phase Ib/II

2. Information about the drug that will be tested in the study	
Name of drug	ACI-24.060
Administration	Participants with prodromal Alzheimer's disease will either receive injections of the study treatment ACI-24.060 alone or ACI-24.060 with an additional adjuvant or placebo at predefined time points over 48 or 74 weeks respectively. Participants with Down syndrome will receive injections of ACI-24.060 or placebo at predefined time points over 74 weeks. The active study treatment is designed to help the immune system produce antibodies against Abeta plaques that are accumulating in the brain of people with Alzheimer's disease.
Is the drug already on the market for another medical condition?	No

Will all participants receive the same drug?	The study in which participants with prodromal Alzheimer's disease will take part, will contain 2 parts:
	
	• Part 1a: participants will be randomly assigned to one of the two groups receiving injections over 48 weeks of either:
	  ○ ACI-24.060
	  ○ or placebo (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested with no active therapeutic effect)
	• Part 1b: participants will be randomly assigned to one of the two groups receiving injections over 74 weeks of either:

	○ ACI-24.060 with an additional adjuvant (substance added to a medicine to help boost the response of the immune system) ○ or placebo Participants with Down syndrome will be randomly assigned in Part 2 of the study, to one of the two groups receiving injections of either: ○ ACI-24.060 • or placebo. The probability to receive either the active study treatment or placebo is predefined in the study protocol and is also mentioned in the informed consent form. Neither the participant nor their doctor will know if the study participant 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 assess the safety, tolerability, immunogenicity (capability of the study treatment to generate antibodies against Aβ proteins which are accumulating in plaques in the brain of study participants) and pharmacodynamic effects (the properties of the biological effect generated by the by the study treatment in participants) of ACI-24.060 in people with prodromal Alzheimer's disease and in people with Down syndrome.
How long will the treatment last?	• 48 weeks for participants with prodromal Alzheimer's disease (Study part 1a) • 74 weeks for participants with prodromal Alzheimer's disease (Study part 1b) • 74 weeks for participants with Down syndrome (Study part 2) • After the completion of the treatment period, the participants will be followed in the study for an additional 26 weeks, respectively

	up to week 74 or week 100 in people with prodromal Alzheimer's disease, and up to week 100 in people with Down syndrome.
What your involvement will entail?	During the study, participants will be asked: • To complete a test that will assess their suicidal ideation behaviour (this is a test called C-SSRS) • To complete some laboratory/biological tests (i.e. blood tests) 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 functioning, cognition and memory related to the study part participants are taking part (i.e. tests like CDR, RBANS, ADAS-Cog 13, mCRT, CANTAB-PAL) • Participants will be asked to undertake brain scans (PET, MRI) Further information on the procedures, tests and 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 study Part 1, participants with prodromal Alzheimer's disease must (main inclusion criteria): • Between 50 and 85 years old • Have evidence of abnormal accumulation of amyloid in their brain (PET scan) • Have a score of 0.5 in the Clinical Dementia Rating-Global Score (CDR). This would suggest that the person has an impairment in its memory and functional capabilities that are at a mild stage

	• If the person is taking approved medication for Alzheimer's disease (ACHEI and/or memantine) the dosing regimen must have been stable for at least 2 months prior to the baseline visit. To take part in study Part 2, participants with Down syndrome must (main inclusion criteria): • Be 35 to 50 years old. Participants between 35 and 39 years old may be considered on the condition that there is amyloid evidence (at PET and/or in body fluids) compatible with Alzheimer's Disease pathology. • Have a cytogenetic diagnosis of Down's syndrome (trisomy 21 or complete unbalanced translocation of the chromosome 21). • Have mild to moderate intellectual disability as per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) classification. All participants must have a study partner who has direct and regular contact, at least 10 hours per week, with the participant and who is able to provide reliable answers to questions related to the participant, according to the study investigator.
Who cannot participate in the study?	People cannot take part in the study if they have or have experienced (main exclusion criteria): • A medical condition that may interfere with the safety and/or efficacy of the study treatment (e.g. moderate and/or severe untreated obstructive sleep apnea, clinically significant reduction in serum B12 or folate levels, clinically significant abnormalities of thyroid function, stroke, or other cerebrovascular conditions). • History of brain diseases including neurological disorders. A more detailed list can be obtained from the study team.

	• Alcohol or drug abuse or dependence within the past 5 years. • Concomitant or past history of psychiatric or neurologic disorder other than those considered to be related to Alzheimer's disease (e.g. head injury with loss of consciousness, symptomatic stroke, Parkinson's disease, severe carotid occlusive disease, transient ischemic attacks haemorrhagic and/or non-haemorrhagic stroke). • Significant risk of suicide. • Positive HIV test or Active hepatitis B and/or C. • Ongoing treatment with any approved anti-amyloid passive immunotherapy for Alzheimer's disease. • Previous treatment with ACI-24 or any other active immunotherapy against Alzheimer's disease. • Previous treatment with any investigational and/or marketed passive immunotherapy against Alzheimer's disease within 6 months before study participation. • Use of symptomatic treatments of Alzheimer's disease (e.g. acetylcholinesterase inhibitors or glutamatergic drugs such as donepezil, rivastigmine, galantamine or memantine) if not on a stable dose for at least 2 months before screening. Additional main exclusion criteria for people with Down syndrome (study part 2): Clinical diagnosis of Alzheimer's disease dementia in Down's syndrome as per International Classification of Diseases 10 (ICD-10).

5. Where and when will the study be conducted?	
European countries involved in the trial	• Spain • UK
Start date of recruitment	June 2022

6. Information for your doctor			
EU-CT Number	2022-500069-29-00	**Clinicaltrials.gov identifier**	NCT05462106
Study contact information	clinicaltrials@acimmune.com +41 21 345 9121		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05462106		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) in September 2026.

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