Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

COGNIS STUDY

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COGNIS study

1. Study Information	
Name of the study	Combined metabolic activator supplementation in subjects diagnosed with Alzheimer's disease
Study sponsor	ScandiBio Therapeutics AB
Disease	Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	Dietary supplementation with CMA2 (including vitamins and amino acids: N-acetyl-L-cysteine (NAC), L-carnitine-L-tartrate (LCAT), nicotinamide (niacinamide), and L-serine))
Administration	Soluble powder to be dissolved in 200 ml preferably cold water before use. The powder can also be used on yoghurt or other food. Participants will take two daily oral doses, one dose just after breakfast and one dose just after dinner.
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • CMA2 • Placebo (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested with no active therapeutic effect). Placebo will contain primarily collagen and maltodextrin. 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 efficacy, tolerability and safety of dietary supplementation in people with Alzheimer's disease
How long will the treatment last?	• 26 weeks with 4 visits to the clinic for check-ups and tests

What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their memory, cognition and activities of daily living (MMSE, ADAS-Cog, ADCS-ADL) • Complete some laboratory tests and neurological examination to evaluate the emergent adverse events (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study). 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 the study, participants must: • Be 50 years old and older • Have a diagnosis of Alzheimer's disease • Have a score above 12 on the ADAS-Cog scale and above 4 on the GDS scale, suggestive of depression and indicating cognitive impairment • Female participants of childbearing potential must have documented tubal ligation or hysterectomy; or be post-menopausal • Have a study partner who is willing to participate in study procedures throughout the study duration
Who cannot participate in the study?	Exclusion criteria include: • A disease that may interfere with the safety or study assessments (e.g., uncontrolled diagnosed depression, uncontrolled diabetes, chronic diarrhoea, chronic kidney disease)

	• History of stroke • History of brain trauma < 14 days • Use of dietary supplements such as vitamins and omega-3 products • Drug and/or alcohol abuse. 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 involved in the trial)	• Turkey
Estimated start date of recruitment	September 2025

6. Information for your doctor	
Clinicaltrials.gov identifier	NCT07062198
Study contact information	Sibel Ertan Phone Number: +905332722936 Email: sertan@kuh.ku.edu.tr
Link to full text	https://clinicaltrials.gov/study/NCT07062198

✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov) in November 2025.