Alzheimer Europe

Making dementia a priority:
changing perceptions, practice and policy.

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

CAFCA STUDY

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CAFCA study

1. Study Information	
Name of the study	Effect of caffeine on cognition in Alzheimer's disease
Study sponsor	University Hospital, Lille
Disease	Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	Caffeine
Administration	2 capsules per day during 27 weeks
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 oral capsule of Caffeine (200mg) twice daily • An oral capsule of placebo (inactive substance identical in appearance to the drug being tested) twice daily. 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 effect of 30-week caffeine treatment on cognition in Alzheimer's disease at beginning to moderate stages.
How long will the treatment last?	• 30 weeks
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their memory, learning, functioning (i.e. tests like NTB, MMSE, DAD) • Complete some laboratory tests.

	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 years old and older • Have a diagnosis of probable Alzheimer's disease according to the National Institute on Aging/Alzheimer's Association core clinical criteria • Have a score >16 points in the MMSE test (a test about your memory). This would suggest that the person has an impairment in their memory that is at a mild stage • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration • If the person is taking treatment for Alzheimer's disease (donepezil, rivastigmine, galantamine, memantime), the dosing regimen must have been stable within the past 2 months and must remain stable for the duration of the study.
Who cannot participate in the study?	Exclusion criteria include: • Participant who refuse to adopt a low caffeine diet (i.e. eviction of tea and caffeinated coffee) • Ongoing neurological disorders, major psychiatric disorder, systematic vascular disease, intracranial mass or medical condition that may interfere with the safety or study assessments or could be the cause of the cognitive impairment • Severe heart disease or rhythm disorder • Active smoking

	• A pregnancy 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
Estimated start date of recruitment	February 2022

6. Information for your doctor			
EudraCT Number:	2019-003302-27	**Clinicaltrials.gov identifier**	NCT04570085
Study contact information	Thibaud LEBOUVIER 0033 3 20 44 60 21 thibaud.lebouvier@chru-lille.fr		
Link to full text	https://www.clinicaltrials.gov/ct2/show/NCT04570085		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on March 2022.
- ✓ 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.