Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

CHOLINE-2 STUDY

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CHOLINE-2 study

1. Study Information	
Name of the study	Donepezil versus non-drug treatment in Alzheimer's disease
Study sponsor	Assistance Publique - Hôpitaux de Paris
Disease	Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	Donepezil
Administration	1 capsule per day
Is the drug already on the market for another medical condition?	Yes – symptomatic drugs for Alzheimer's disease
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • Standard of care, non-drug approach: following the recommendations of the Alzheimer's disease care by the French Health Authority. The care is cognitive, psychic, functional or social and centered on the patient and his environment. This care is best carried out by the memory consultations participating in this study and having extensive experience in the care of Alzheimer patients. • Donepezil group: Management similar to the previous arm plus addition of Donepezil (5mg) per day during one month and then an oral capsule of Donepezil (10 mg) per day until months 6. 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 compare the efficiency of the two approaches (non-drug versus donepezil) on the symptoms of Alzheimer's disease after six months of treatment.

How long will the treatment last?	• 6 months
What your involvement will entail?	• During the study, participants will be asked to complete some tests that will assess their memory, functioning, behaviour, quality of life and other health-related questionnaires (i.e. tests or scales like MMSE, CDR, 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 years old and older • Have a diagnosis of probable Alzheimer's disease according to International Working Group (IWG) 2 Criteria for Alzheimer's Disease Diagnosis, including positivity of biomarkers in the cerebrospinal fluid (CSF) • Have a score >10 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 or prodromal stage. • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration • Be French native speaker.
Who cannot participate in the study?	Exclusion criteria include: • Ongoing disorders that may cause dementia • Severe heart disease that may interfere with the safety or study assessments (i.e. bradycardia)

	• Previous use of symptomatic treatment for Alzheimer's disease • Participation in another clinical study. 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	
Clinicaltrials.gov identifier	NCT04661280
Study contact information	DUMURGIER Julien 0033 1 40 05 43 13 julien.dumurgier@aphp.fr PAQUET Claire claire.paquet@inserm.fr
Link to full text	https://www.clinicaltrials.gov/ct2/show/NCT04661280

- ✓ 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.