Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

AB21004 STUDY

Alzheimer Europe A.S.B.L. • R.C.S. Luxembourg F2773 • 14, rue Dicks • L-1417 Luxembourg
Tel.: +352-29 79 70 • Fax: +352-29 79 72 • info@alzheimer-europe.org • www.alzheimer-europe.org

AB21004 study

1. Study Information	
Name of the study	Masitinib in patients with mild to moderate Alzheimer's disease
Study sponsor	AB Science
Disease	Mild to moderate Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	Masitinib
Administration	Oral administration twice daily in addition to symptomatic treatment medications for Alzheimer's disease such as cholinesterase inhibitor (donepezil, rivastigmine or galantamine) and /or memantine
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: • Masitinib with an initial dosage of 3.0mg/kg/day which will be increased to 4.5mg/kg/day after 4 weeks of treatment • Placebo (also called a dummy treatment which is an inactive 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 confirm the treatment effect with masitinib alongside other medications like cholinesterase inhibitor and/or memantine in people with mild-to-moderate Alzheimer's disease
How long will the treatment last?	• 24 weeks

	• All participants can then enter an extension phase of 24 weeks
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their cognition and activities of daily living (i.e. ADAS-Cog, ADCS-ADL) • Complete other tests that will assess their cognition, memory, and behaviour (i.e. tests such as CDR-SB, MMSE) • During the study, participants will have to undergo brain scan (MRI, PET) 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 clinical diagnosis of Alzheimer's disease according to the International Working Group criteria • Have a score between 14-25 points in the MMSE test (a test about a range of everyday mental skills). This would suggest that the person has an impairment that is at a mild to moderate stage • Have results of brain scans (MRI) consistent with the clinical diagnosis of Alzheimer's disease • The dosing regimen of the symptomatic treatment medications for Alzheimer's disease such as cholinesterase inhibitors (donepezil, rivastigmine or galantamine) and/or memantine must have been stable within the past 6 months

	• If the person is receiving a supplement for cognition (e.g., gingko biloba, omega-3 polyunsaturated fatty acid, vitamin E, curcumin, souvenaid), the dosing regimen must have been stable for a least 4 months
Who cannot participate in the study?	Exclusion criteria include: • Any evidence of another form of dementia • Systemic conditions known to cause dementia (i.e. hypothyroidism, untreated vitamin B12 or folic acid deficiency, niacin deficiency, neurosyphilis, HIV infection) • A disease or medical condition that may interfere with the study assessments and will make the participant unsuitable for participation in or completion of the trial procedures (i.e. delirium, psychosis, psychiatric disorder, delusions) 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 that involved in the trial (active)	• Spain
European countries that will be involved in the trial (planned)	• France • Greece
Estimated start date of recruitment	February 2023

6. Information for your doctor			
EudraCT Number:	2021-002179-21	**Clinicaltrials. gov identifier**	NCT05564169
Study contact information	clinical@ab-science.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05564169		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on April 2023.
- ✓ This document has been reviewed by the pharmaceutical company running this trial.
- ✓ This document has been reviewed by a member of the European Dementia Carers Working Group.