Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

NanoLi_AD STUDY

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NanoLi_AD study

1. Study Information	
Name of the study	A prospective, multicenter, with a first randomised, placebo-controlled, parallel-group, double-blind period followed by an open-label trial period to evaluate the clinical safety and efficacy of NanoLithium® NP03 in patients with mild-to-severe Alzheimer's disease: a proof-of-concept study
Study sponsor	Medesis Pharma SA
Disease	Mild to severe Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	NanoLithium® NP03
Administration	Yellow oily liquid to be administrated orally in the mouth (gingivo-jugal groove of each cheek) with the pipette once daily.
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	During the first part of the study (12 weeks), participants will be selected by chance to receive one of the following options: • An oro-muccosal administration of NanoLithium® NP03 (3 mL per day & 1.8 mg/day) by a buccal deposit of 1.5mL in each cheek • An oro-muccosal administration of placebo by deposit in the cheek (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. During the second part of the study (36 weeks), all participants will receive an oro-muccosal administration of NanoLithium® NP03 (3 mL per day & 1.8 mg/day) by a buccal deposit of 1.5mL in each cheek.

3. Information about participating in the trial	
What are the researchers trying to find out?	• The purpose of the study is to evaluate the safety and efficacy of NanoLithium® NP03 in people with mild-to-severe Alzheimer's disease.
How long will the treatment last?	• Approximately one year
What your involvement will entail?	• During the study, participants will be asked to complete a test that will assess their dementia-related behavioral symptoms such as hallucinations, agitation (this is a test called NPI) • To complete some laboratory/biological tests (i.e. blood tests, ECG, blood pressure, pulse rate) 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 neuropsychiatric symptoms, activities of daily living and memory (i.e. tests like MMSE, CDR, ADL) • Participants will be asked to undertake brain scans (PET). A total of 18 clinical or phone call visits are scheduled during this study. Further information 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 to 90 years old male or female • Have a diagnosis of Alzheimer's disease according to the international diagnosis criteria from McKhann G. M. et al. (2011)

	• Clinical significant behavioural and psychological symptoms of dementia (BPSD) requiring medication in the opinion of the study specialist • Have a score of between 10 and 26 in the MMSE test questionnaire test (a test about your memory). This would suggest that the person has an impairment in their memory that is at a mild to severe stage • Symptomatic treatments of Alzheimer's disease (e.g. acetylcholinesterase inhibitors and memantine) and psychotics drugs (e.g. benzodiazepines, antidepressants, anxiolytics, neuroleptics) are allowed but need to be maintained during at least 4 weeks before inclusion and during the entire study • Be willing to use contraception during the study • Have a study partner who has a sufficient and frequent contact with the participant, is willing to participate in study procedures throughout the study duration and provide accurate information regarding the patient's behavior, cognitive, and functional abilities as well as his/her health throughout the study • Be willing and able to give informed consent. If the participant is not competent, a legally authorised representative must provide informed consent on his/her behalf, and the participant must provide assent • Be willing to and can comply with the study protocol requirements, in the opinion of the investigator • If the patient took part to another therapeutic clinical trial, he/she must systematically observe a wash-out period of >

	4 weeks, or of > 6 months if he/she received a biologic disease modifying treatment (antibodies targeting the β-amyloid protein or the p-Tau protein) • Participants must be affiliated to French social security.
Who cannot participate in the study?	Exclusion criteria include: • Participants with genetic form of Alzheimer's disease (known genetic mutation) • Participants with major physical or neurosensory problems likely to interfere with the tests; contraindication or refusal to perform functional brain imaging examinations • Absence of a study partner to complete psychological and behavioural scales and/or questionnaires • Participants with illiteracy and/or inability to perform psychological and behavioural evaluations • A pathology involving short term vital prognosis (e.g. progressive cancer, unstable heart failure, severe liver, kidney or respiratory diseases) • Any alcohol or drug abuse • A pregnancy or breast-feeding for female participants • Epilepsy or other neurodegenerative disorders • Vitamin B12 or folic acid deficiency without supplementation • Participation in another drug trial • Participants with thyroid disorders not treated • Participant living in institution • Participant with contraindications to drugs containing lithium such as heart failure, renal failure, Addison disease and Brugada syndrome. 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	• France
Estimated start date of recruitment	May 2022

6. Information for your doctor	
Clinicaltrials.gov identifier	NCT05423522
Study contact information	Solène GUILLIOT +33 4 67 10 71 60 solene.guilliot@medesispharma.com Maria SOTO MARTIN +33 5 61 77 64 26 soto-martin.me@chu-toulouse.fr
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05423522

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on July 2022.
- ✓ The pharmaceutical company running this trial has reviewed this document.