Alzheimer Europe

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CLINICAL TRIALS WATCH

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ADvance II 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

ADvance II study

1. Study Information	
Name of the study	Deep Brain Stimulation of the Fornix in patients with mild Alzheimer's disease
Study sponsor	Functional Neuromodulation Ltd
Disease	Mild Alzheimer's disease
Phase	Not applicable – Procedural intervention (brain stimulation)

2. Information about the intervention that will be tested in the study	
Name of the intervention	Deep Brain Stimulation of the fornix
Administration	The intervention will be administered via a deep brain stimulation targeting the Fornix (a minimally invasive surgical method in which stimulation electrodes are implanted into the specific area of the brain named fornix).
Is the intervention already on the market for another medical condition?	No
Will all participants receive the same intervention?	Participants will be selected at random to either receive one of the following options: • Brain stimulation of the fornix • No brain stimulation. Neither the participant nor their doctor will know if the person is receiving the brain stimulation or not.

3. Information about participating in the study	
What are the researchers trying to find out?	• The purpose of the study is to evaluate the safety and efficacy of Deep Brain Stimulation of the fornix in people with mild probable Alzheimer's disease.
How long will the study last?	• 12 months
What your involvement will entail?	• Participants will be asked to complete a test that will assess their memory, orientation, judgment and problem solving, personal care and community affairs (this is a test called CDR-CB)

	• Participants will be also requested to complete some tests to evaluate impaired function and possible cognitive impairment (i.e. iADRS). Further information on the procedures, tests and 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 65 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 of 0.5 to 1 in the Clinical Dementia Rating-Global Score (CDR) at screening suggesting a questionable dementia or mild cognitive impairment • Have results of lumbar puncture (spinal tap) with findings consistent with a diagnosis of Alzheimer's disease • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration • Be a good surgical candidate for placement of a deep brain stimulator as judged by the clinical team • If the person is taking acetylcholinesterase inhibitors as an approved Alzheimer's disease medication (i.e. donepezil, rivastigmine, galantamine) the dosing regimen must have been stable for at least 60 days prior to signing the consent form and must be stable during the 12-month control period of the study.

Who cannot participate in the study?	Exclusion criteria include: • Have a total score >10 in the Neuropsychiatric Inventory test (NPI) or a score >4 in any NPI domain (a questionnaire used to assess behavioral domains). This would suggest that the person has severe behavioural disturbances • Suicidal behaviour in the opinion of the investigator • An unstable medical condition that may interfere with the safety, tolerability and/or study assessments (e.g. cardiac, respiratory disease, hallucinations, major depression, brain tumor) • Have any contraindication to brain scans (due to having prostheses, implants, a pacemaker or claustrophobia) • Currently prescribed any non-Alzheimer's disease medications, that may interfere with the safety, tolerability and/or study assessments • Ongoing 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 country involved in the trial	• Germany
Estimated start date of recruitment	August 2019

6. Information for your doctor	
Clinicaltrials.gov identifier	NCT03622905
Study contact information	Kristen Drake - kdrake@fxneuromod.com Lisa Fosdick - lfosdick@fxneuromod.com
Link to full text	https://www.clinicaltrials.gov/ct2/show/NCT03622905

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