Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

FEAD STUDY

Alzheimer Europe • R.C.S. LUXEMBOURG F2773 • 5 Heienhaff, L-1736 Senningerberg
Tel. +352 29 79 70 • Fax +352 29 79 72 • info@alzheimer-europe.org • www.alzheimer-europe.org

FEAD study

1. Study Information	
Name of the study	A placebo controlled randomized double-blind parallel group 12-month trial of Fasudil for the treatment of early Alzheimer's disease (FEAD)
Study sponsor	Helse Stavanger HF
Disease	Early Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	Fasudil hydrochloride
Administration	Oral tablet 3-times daily
Is the drug already on the market for another medical condition?	Fasudil is approved in Japan and China for the treatment of cerebral vasospasm, often following a bleed on the brain.
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • Oral tablet of Fasudil • Oral tablet of 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 evaluate the efficacy and safety of Fasudil for the treatment of early Alzheimer's disease.
How long will the treatment last?	• 12 months
What your involvement will entail?	• During the study, participants will be asked to complete some tests that will assess cognition, memory, attention, executive functions and daily living activities

	• To undergo brain scans (e.g. MRI, PET) and lumbar puncture (CSF) • To provide blood and urine samples for laboratory analysis. Safety laboratory tests, will be performed to assess various health parameters. Further information on the procedures, tests and 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 between 50 and 100 years old • Have a diagnosis of early Alzheimer's disease (mild cognitive impairment of mild Alzheimer's disease dementia) • Have evidence of abnormal accumulation of amyloid or tau in the brain (determined either through CSF examination (lumbar puncture) or with the use of an amyloid PET scan) • Have a score of 0.5 or 1 in the Clinical Dementia Rating Global Score (CDR) • Have results of an MRI scan within the past two years that has no findings inconsistent with 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 • Fluent in Norwegian.

Who cannot participate in the study?	Exclusion criteria include: • A disease or condition that may interfere with the safety, tolerability and/or study assessments (e.g., depression, mental disorder) • Significant brain injuries or disease such as stroke, cortical infarction, etc.. • A history of severe bleeding of the digestive tract, lungs, nose or skin • Severe kidney impairment or moderate to severe liver impairment • Currently poorly controlled diabetes • Clinically significant hypotension • If the person is taking approved symptomatic medication for dementia (i.e. cholinesterase inhibitors or memantine) or anti-depressive drugs, the dosing regimen must have been stable for at least three months prior before the study • Participation in other drug trials • Currently ongoing life-threatening disease, such as metastatic cancer, advanced cardiovascular disease, advanced respiratory disease, terminal kidney disease, or advanced stages of infectious diseases. 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 will be involved in the trial (planned)	• Norway
Estimated start date of recruitment	June 2024

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT06362707	**EU CT Number**	2023-506514-44-00
Study contact information	Dag Aarsland, +4797575804 daarsland@gmail.com Nicolas Castellanos Perilla, +4741279857 nicolascastellanos1107@gmail.com		
Link to full text	https://clinicaltrials.gov/study/NCT06362707		

✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on July 2024.

✓ This document has been reviewed by the sponsor running this trial.

✓ This document has been reviewed by a member of the European Dementia Carers Working Group.