Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

The **ANeED** Study

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The ANeED study

1. Study Information	
Name of the study	**A**mbroxol in **N**ew and **E**arly patients with prodromal and mild **D**ementia with Lewy bodies (ANeED)
Study sponsor	Helse Fonna
Disease	Prodromal and early dementia with Lewy bodies (DLB)
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	Ambroxol
Administration	Oral tablet of ambroxol, three times a day
Is the drug already on the market for another medical condition?	Yes, it is a drug used to treat airway mucus hypersecretion and the main ingredient of cough medicines.
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • tablets of ambroxol. Participants will receive escalating doses of ambroxol (starting from 60mg three times per day the first week to 420mg three times per day the last week of treatment). • tablets 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 effects on cognition, functional decline and on neuropsychiatric symptoms of ambroxol in people with prodromal and mild dementia with Lewy Bodies.

How long will the treatment last?	The study consists of a treatment period of 18 months. Participants who complete the treatment period will be offered enter an open extension period for an additional year.
What your involvement will entail?	• During the study, participants will be asked to complete some tests that will assess their cognition, behaviour, function and neuropsychiatric symptoms (MMSE, ADCS-CGIC, CDR-SB, NPI, GDS) • To complete other tests to evaluate sleep disturbances, falls fluctuations and parkinsonism (MSQ, MFS, UPDRS-III) • Participants will undergo lumbar puncture (CSF) and brain scans (MRI) • Do physical examination including an electrocardiogram (ECG), which is a test that records the electrical activity of the heart and an electroencephalogram (EEG), which is another test that measures electrical activity in the brain • Complete some laboratory tests (blood) and neurological examination to evaluate the emergent adverse events (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study). Each participant will undergo 8 hospital visits and 16 telephone visits after 2 screening visits during the first 18 months. 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 85 years old

	• Have a confirmed diagnosis of dementia with Lewy Bodies (DLB) or Mild Cognitive Impairment in DLB (DLB-MCI) • Have a score greater than 15 in the MMSE score. This would suggest that the person has an impairment in their memory that is at a mild to moderate stage • Women of non-childbearing potential (surgically sterilised or post-menopausal). Women of child-bearing potential must use accepted contraceptive methods • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration.
Who cannot participate in the study?	Exclusion criteria include: • Current treatment with anticoagulants or a disease/ condition that may interfere with the safety, tolerability and/or study assessments (e.g., major depression, schizophrenia, stroke, trauma, hepatic impairment, metastatic cancer) • Current use of investigational medicinal product or participation in another interventional clinical trial (or within the past 30 days) • Confirmed dysphagia that would preclude self-administration of treatment • History of known rare hereditary disorders of galactose intolerance • History of alcohol or drug abuse

	• Donation of blood within three months prior to receiving the first dose of the study drug • Pregnancy or breastfeeding • Planned major surgery or other major treatments during study period that will interfere with study-obligations. 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	• Norway
Estimated start date of recruitment	June 2022

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT04588285	**EU CT Number**	2019-002855-41
Study contact information	Arvid Rongve arvid.rongve@helse-fonna.no		
Link to full text	https://clinicaltrials.gov/study/NCT04588285		

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

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

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