Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ASURE STUDY

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ASURE study

1. Study Information	
Name of the study	Alzheimer Study Using oRal Edaravone
Study sponsor	Treeway B.V.
Disease	Mild Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	TW001 (also called Edaravone)
Administration	The drug will be administered in a fasted state via an oral dose once daily.
Is the drug already on the market for another medical condition?	Yes - antioxidant drug marketed in the US and Japan to treat amyotrophic lateral sclerosis.
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • An oral dose of TW001 (100mg) • An oral dose 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 safety, pharmacodynamics and pharmacokinetics of TW001 in people with mild Alzheimer's disease.
How long will the treatment last?	• The treatment lasts 90 days • The total duration of the clinical trial will be approximately four months per participant.

What your involvement will entail?	• During the study, participants will be asked to complete some laboratory and biological tests such as blood and urines tests • Participants will be asked to complete tests that will assess cognition, memory and behaviour (i.e. tests like CDR-SB, MMSE) • Participants will also undergo lumbar puncture (CSF). 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 55 and 80 years old • Have a body mass index between 18.5 to 30.0 kg/m^2 • Have a diagnosis of early Alzheimer's disease according to the National Institute on Aging/Alzheimer's Association (NIA-AA) core clinical criteria • Have a score of 20 or above in the MMSE test (a test about memory). This would suggest that the person has an impairment in their memory that is at a mild stage • Have gradual and progressive change in memory function over more than 6 months • Have evidence of abnormal accumulation of amyloid and Tau in the brain (as per results of CSF, PET scan) • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration

	• If the person is taking medication, supplements or vitamins that may have an influence on the study, the dosing regimen must have been stable for a least one month and the person must be willing to remain on the same treatment and dose for the duration of the trial • Use highly effective contraception • Women of non-childbearing potential (surgically sterilized or post-menopausal).
Who cannot participate in the study?	Exclusion criteria include: • 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, stroke, uncontrolled or significant cardiac disease, cancer) • Any diagnosis of relevant neurological disorder other than Alzheimer's disease such as vascular dementia, frontotemporal dementia, Parkinson's disease, dementia with Lewy Bodies, Huntington's disease • History of stroke, renal impairments, hepatic disease • History of seizures or epilepsy within the past 5 years • Positive HIV test or Active hepatitis B and/or C • Any alcohol or drug abuse or dependence • Treatment with any investigational drug within the past 30 days. 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	• Netherlands
Estimated start date of recruitment	January 2023

6. Information for your doctor			
EudraCT Number	2021-003164-27	**Clinicaltrials.gov identifier**	NCT05323812
Study contact information	Frank Ruwe +31625375343 frank@treeway.nl Anastasia Lili +31644620205 anastasia@treeway.nl		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05323812		

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