Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

REMAD-02 STUDY

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REMAD-02 study

1. Study Information	
Name of the study	A Phase 2a study to investigate REM0046127 in mild to moderate Alzheimer's disease
Study sponsor	reMYND
Disease	Mild to moderate Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	REM0046127
Administration	The drug will be administered via an oral suspension twice daily for 28 days.
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	Participants with prodromal Alzheimer's disease will be selected by chance to receive one of the following options: • An oral suspension of REM0046127 at high dose (1400mg; 700mg bid) • An oral suspension of REM0046127 at low dose (350mg; 175mg bid) • An oral suspension 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, tolerability and effects of REM0046127 in people with mild to moderate Alzheimer's disease.
How long will the treatment last?	• 2 months

	• Each participant will start with a 14-day placebo run-in period, followed by a 28-day treatment period with REM0046127 and finally a 7-day follow-up period.
What your involvement will entail?	• During the study, participants will be asked to complete a questionnaire that will evaluate their cognitive impairment (this is a test called MMSE) • To complete some laboratory/biological tests to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • Participants will be asked to perform electroencephalogram (EEG), a test that measure electrical activity in the brain • Participants will be asked to undertake brain scans (e.g., MRI) 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 with prodromal Alzheimer's disease must: • Be 50 to 85 years old • Have a diagnosis of mild to moderate Alzheimer's disease according to the National Institute on Aging/Alzheimer's Association core clinical criteria • Have a score above 12 (preferable above 16) and a maximum of 24 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 moderate stage

	• Have evidence of abnormal accumulation of amyloid in their brain (brain scan) • Have a body mass index (BMI) between 18 and 25 • If the person is talking concomitant medications, the dosing regimen must have been stable for a least 3 months prior to the baseline visit and is expected to remain stable during the conduct of the study • If the person is taking approved symptomatic medication for dementia (i.e. donepezil, rivastigmine, galantamine or memantine) the dosing regimen must have been stable for at least 6 months prior to the baseline visit • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration • Be able to read, write, speak clearly for the cognitive tests.
Who cannot participate in the study?	Exclusion criteria include: • COVID-19 positive test at the baseline visit • A disease or condition that may interfere with the safety, tolerability and/or study assessments (e.g. other types of dementia or neurogenerative diseases, syphilis, vitamin B12 or folate deficiency, neoplasia) • History of severe post-lumbar puncture syndrome • Abnormalities in the blood clotting system or abnormal coagulation status

	• Women of childbearing potential or male subjects with female partners of child-bearing potential who are unwilling or unable to adhere to contraception requirements • Participation in another clinical study during the last 3 months • Wheelchair-bound or bed-ridden. 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 countries involved in the trial	• Netherlands • Spain
Estimated start date of recruitment	July 2022

6. Information for your doctor			
EudraCT Number	2022-000080-43	**Clinicaltrials.gov identifier**	NCT05478031
Study contact information	Mieke Nuytten - +3216751420 mieke.nuytten@remynd.com Philipp Temel - +4366488869902 ptemel@neuroscios.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05478031		

✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on November 2022.