Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

VIVIAD STUDY

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VIVIAD study

1. Study Information	
Name of the study	A study to evaluate safety and tolerability of different doses and efficacy of PQ912 in subjects with mild cognitive impairment and mild Alzheimer's disease
Study sponsor	Vivoryon Therapeutics AG
Disease	Alzheimer's disease
Phase	Phase IIb

2. Information about the drug that will be tested in the study	
Name of drug	PQ912 (also named varoglutamstat)
Administration	Tablet
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • An oral tablet of PQ-912 once daily (evening) • An oral tablet of placebo (inactive substance identical in appearance to the drug being tested). 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 efficacy of PQ912 in people with mild cognitive impairment and mild dementia due to Alzheimer's disease.
How long will the treatment last?	• The duration of participation in the study is either 48, 60, 72, 84 or 96 weeks of treatment.
What your involvement will entail?	• During the study, participants will have to undergo brain scan (MRI) to see if they have amyloid pathology in their brain • Complete some laboratory tests and neurological

	examinations to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • During the study, participants will be asked to complete other tests that will assess their memory, functioning, attention and psychomotor function (i.e. tests or scales like CBB-Z, NTB) • Do physical examination and an electroencephalography (a test that records the electrical activity of the brain). Further information on the 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 50 to 80 years old • Have a diagnosis of mild cognitive impairment or mild Alzheimer's disease according to the National Institute on Aging/Alzheimer's Association core clinical criteria • Have adequate visual and auditory abilities to perform the cognitive and functional assessments in the opinion of the investigator • 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: • Any other type of neurological or psychiatric disease that is not Alzheimer's disease (e.g. epilepsy) that may affect cognition • History of schizophrenia (mental disorder which affects how a person thinks, feels and acts) or other depressive

	disorder • History of a stroke, transient ischemic attack or seizures within the past two years • Contraindication to MRI procedures and lumbar puncture. 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 (active)	• Denmark • Germany • Netherlands • Spain
Estimated start date of recruitment	July 2020

6. Information for your doctor			
EudraCT Number:	2019-003532-23	**Clinicaltrials.gov identifier**	NCT04498650
Study contact information	Katharina Fuchs +49 5559900 Kerstin Kuehn-Wache +49 5559900 clinics@vivoryon.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT04498650		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on May 2022.
- ✓ This document has not been reviewed by the pharmaceutical company running this trial.
- ✓ This document has been reviewed by a member of the European Working Group of People with Dementia.