Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

Brainshuttle AD STUDY

Alzheimer Europe A.S.B.L. • R.C.S. Luxembourg F2773 • 14, rue Dicks • L-1417 Luxembourg
Tel.: +352-29 79 70 • Fax: +352-29 79 72 • info@alzheimer-europe.org • www.alzheimer-europe.org

Brainshuttle AD study

1. Study Information	
Name of the study	A multiple ascending dose study to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of RO7126209 following intravenous infusion in participants with prodromal or mild to moderate Alzheimer's disease
Study sponsor	Hoffmann-La Roche
Disease	Prodromal or mild to moderate Alzheimer's disease
Phase	Phase I/II

2. Information about the drug that will be tested in the study	
Name of drug	RO7126209
Administration	The drug will be administered via an intravenous infusion (an injection into the vein) once every 4 weeks
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 intravenous infusion of RO7126209 (one of the four doses) • An intravenous infusion of placebo (a substance which looks like the trial drug but has no study drug in it). 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 this study is to evaluate the safety and tolerability of multiple-ascending intravenous doses of RO7126209 in people with prodromal or mild to moderate Alzheimer's disease, who are amyloid positive based on amyloid positron emission tomography (PET) scan.

How long will the treatment last?	• 28 weeks of treatment followed by a 28-week safety follow-up period.
What your involvement will entail?	• During the study, participants will have to complete a PET brain scan or CSF examination (lumbar puncture) to see if they have amyloid pathology in their brain • Complete some laboratory tests (i.e. blood pressure, heart rate) to evaluate the emergent adverse events (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • Complete a test that will assess memory, orientation, judgment and problem solving, personal care and community affairs which is a test called Clinical Dementia Rating (CDR). 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 85 years old • Have a diagnosis of probable mild to moderate Alzheimer's disease according to the National Institute on Aging/Alzheimer's Association core clinical criteria • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration • Have a score of 0.5 to 2 in the Clinical Dementia Rating-Global Score (CDR) and a score of 18 to 28 in the MMSE 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 (PET scan) • If the person is taking approved symptomatic medication for dementia (i.e. donepezil, rivastigmine or galantamine) the dosing regimen must have been stable • Agree to not participate in other clinical studies for the duration of this study.
Who cannot participate in the study?	Exclusion criteria include: • Ongoing neurological disorders, major psychiatric disorder, systematic vascular disease, intracranial mass or medical condition that may interfere with the safety or study assessments or could be the cause of the cognitive impairment • Any other type of disease that may interfere with the study (i.e. hematological, ophthalmologic, cardiovascular diseases) • Brain scans showing significant abnormality • Contraindication to PET imaging, 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	• Spain • Poland
Estimated start date of recruitment	March 2021

6. Information for your doctor

EudraCT Number:	2020-002477-98	**Clinicaltrials.gov identifier**	NCT04639050
Study contact information	global-roche-genentech-trials@gene.com		
Link to full text	https://www.clinicaltrials.gov/ct2/show/NCT04639050		

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