

# **CLINICAL TRIALS WATCH**

**ACCESSIBLE EASY READ INFORMATION ON:**

**VHB937 STUDY**

# VHB937 study

<b>1. Study Information</b>	
<b>Name of the study</b>	A clinical trial to learn about the effects of VHB937 in people with early Alzheimer's disease
<b>Study sponsor</b>	Novartis Pharmaceuticals
<b>Disease</b>	Early Alzheimer's disease
<b>Phase</b>	Phase II

<b>2. Information about the drug that will be tested in the study</b>	
<b>Name of drug</b>	VHB937
<b>Administration</b>	Intravenous infusion
<b>Is the drug already on the market for another medical condition?</b>	No
<b>Will all participants receive the same drug?</b>	<p>Participants will be selected by chance to receive one of the following options:</p> <ul style="list-style-type: none"><li>• An intravenous infusion of VHB937 (low dose)</li><li>• An intravenous infusion of VHB937 (high dose)</li><li>• An intravenous infusion 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).</li></ul> <p>Neither the participant nor their doctor will know if the person is receiving the investigational drug or the placebo.</p>

<b>3. Information about participating in the trial</b>	
<b>What are the researchers trying to find out?</b>	<ul style="list-style-type: none"><li>• The study will evaluate the safety and efficacy of VHB937 in people with early Alzheimer's disease.</li></ul>
<b>How long will the treatment last?</b>	<ul style="list-style-type: none"><li>• Around 1.5 years</li><li>• After the completion of the treatment, participants will be offered to take part in the extension period to continue to receive open-label treatment with VHB937.</li></ul>

<p><b>What your involvement will entail?</b></p>	<ul style="list-style-type: none"> <li>• During the study, participants will be asked to complete tests that will assess their memory, cognition, functional, behaviour and activities of daily living (CDR-SB, ADAS-Cog14, ADCS-ADL-MCI)</li> <li>• Undergo brain scans (PET imaging)</li> <li>• Complete some laboratory tests 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).</li> </ul> <p>Further information on the procedures, tests and number of visits can be obtained from the study team.</p>
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<p><b>4. Who can participate in this study?</b></p>	
<p><b>Who can participate in the study?</b></p>	<p>To take part in the study, participants must:</p> <ul style="list-style-type: none"> <li>• Be between 50 and 85 years old</li> <li>• Has a diagnosis of Mild Cognitive Impairment (MCI) due to Alzheimer's disease or mild Alzheimer's disease according to the NIA-AA criteria</li> <li>• Has a score of 0.5 or 1.0 in the clinical Dementia Rating (CDR) Global score. This would suggest that the person has an impairment in its memory that is at a mild stage</li> <li>• Confirmation of Alzheimer's disease based on cerebral spinal fluid (CSF) biomarkers or amyloid PET imaging</li> <li>• Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration</li> <li>• If the person is taking approved symptomatic medication for Alzheimer's disease (i.e. donepezil, rivastigmine,</li> </ul>

	galantamine or memantine), the dosing regimen must have been stable for at least 12 weeks prior to starting study treatment
<b>Who can't participate in the study?</b>	<p>Exclusion criteria include:</p> <ul style="list-style-type: none"> <li>• Dementia due to a condition other than Alzheimer's disease, including but not limited to, frontal temporal dementia, Parkinson's disease, dementia with Lewy bodies, Huntington disease, vascular dementia</li> <li>• Diagnosis of a clinically relevant central nervous system disease other than dementia (e.g. serious brain infection, traumatic brain injury, multiple concussions, epilepsy or recurrent seizures)</li> <li>• A disease that may interfere with the safety or study assessments (e.g., Human immunodeficiency virus, hepatitis B, hepatitis C, uncontrolled thyroid disease, uncontrolled diabetes. major depressive episode that is not adequately controlled, history of schizophrenia, other chronic psychosis)</li> <li>• History or current diagnosis of cardiac conditions, liver or renal disease/injury</li> <li>• Presence of suicidal ideation within 6 months or suicidal behavior within 2 years before screening.</li> </ul> <p>The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study.</p>

<b>5. Where and when will the study be conducted?</b>	
<b>European country involved in the trial (active)</b>	<ul style="list-style-type: none"> <li>• UK</li> </ul>

<b>European countries that will be involved in the trial (planned)</b>	<ul style="list-style-type: none"> <li>• Czech Republic</li> <li>• France</li> <li>• Germany</li> <li>• Italy</li> <li>• Netherlands</li> <li>• Poland</li> <li>• Spain</li> <li>• Sweden</li> </ul>
<b>Estimated start date of recruitment</b>	October 2025

<b>6. Information for your doctor</b>			
<b>Clinicaltrials.gov identifier</b>	NCT07094516	<b>EUCT Number</b>	2024-516966-12-00
<b>Study contact information</b>	<a href="mailto:novartis.email@novartis.com">novartis.email@novartis.com</a>		
<b>Link to full text</b>	<a href="https://clinicaltrials.gov/study/NCT07094516">https://clinicaltrials.gov/study/NCT07094516</a> <a href="https://euclinicaltrials.eu/ctis-public/view/2024-516966-12-00">https://euclinicaltrials.eu/ctis-public/view/2024-516966-12-00</a>		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov, CTIS websites) in November 2025.
- ✓ This document has been reviewed by a member of the European Dementia Carers Working Group.