

# CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

## NSC001 STUDY

# NSC001 study

## 1. Study Information

<b>Name of the study</b>	A study to assess safety and tolerability and to explore efficacy of NSC001 in mild to moderate Alzheimer's disease
<b>Study sponsor</b>	NSC-Therapeutics
<b>Disease</b>	Mild to moderate Alzheimer's disease
<b>Phase</b>	Phase I/II

## 2. Information about the drug that will be tested in the study

<b>Name of drug</b>	NSC001
<b>Administration</b>	Oral administration once daily
<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>• 40 mg of NSC001</li><li>• 40 mg of NSC001 + 20mg of Trospium</li><li>• Placebo with or without Trospium (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>

## 3. Information about participating in the trial

<b>What are the researchers trying to find out?</b>	<ul style="list-style-type: none"><li>• The purpose of this study is to evaluate the safety and tolerability of NSC001 in people with mild to moderate Alzheimer's disease and to evaluate its influence on cognitive function.</li></ul>
<b>How long will the treatment last?</b>	<ul style="list-style-type: none"><li>• 16 weeks of treatment and 1 week of follow-up</li></ul>
<b>What your involvement will entail?</b>	<ul style="list-style-type: none"><li>• During the study, participants will be asked to complete tests that will assess their memory, cognition, functional, neuropsychiatric symptoms and behaviour (ADAS-Cog, MMSE)</li></ul>

	<ul style="list-style-type: none"> <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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<b>4. Who can participate in this study?</b>	
<b>Who can participate in the study?</b>	<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>• 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>• Female participants must be post-menopausal for at least 2 consecutive years or surgically sterile for at least 6 months</li> <li>• Male participants with partners who are women of childbearing potential must agree to use a reliable means of contraception during the trial and 6 months after discontinuing the trial intervention</li> <li>• Have a clinical diagnosis of mild to moderate dementia, according to the NIA-AA 2018 criteria</li> <li>• Magnetic resonance imaging (MRI) or computed tomography (CT) scan performed within 12 months before screening, with findings consistent with the clinical diagnosis of mild to moderate AD without any other clinically significant comorbid pathologies, especially cerebrovascular lesions.</li> <li>• Has a score between 18 and 26 in the MMSE score. This would suggest that the person has an impairment in its</li> </ul>

	<p>memory that is at a mild to moderate stage</p> <ul style="list-style-type: none"> <li>• Confirmation of a clinical diagnosis of mild to moderate Alzheimer's disease based on Magnetic resonance imaging (MRI) or computed tomography (CT) scan</li> <li>• Use of approved symptomatic medication for Alzheimer's disease (i.e. donepezil, rivastigmine, galantamine), the dosing regimen must have been stable for at least 3 months.</li> </ul>
<b>Who can't participate in the study?</b>	<p>Exclusion criteria include:</p> <ul style="list-style-type: none"> <li>• Prior use of anti-beta-amyloid immunotherapy (e.g., Aducanumab, Leqanemab, Donanemab) or administration of anti-amyloid vaccine</li> <li>• Enrollment in another investigational clinical trial and administration of investigational drug within the previous three months</li> <li>• Current use of anticholinergics, including trospium within the past 2 weeks</li> <li>• Use of the following medications: benzodiazepines, antihistamines, anticonvulsants, antidepressants, antipsychotics or narcotic medications</li> <li>• A disease that may interfere with the safety or study assessments (e.g., human immunodeficiency virus, hepatitis B, hepatitis C, respiratory insufficiency, heart disease, impaired renal function, uncontrolled diabetes, chronic liver disease)</li> <li>• Female participants who are pregnant or currently breastfeeding or who plan to become pregnant</li> </ul>

	<ul style="list-style-type: none"> <li>Male participants with a partner who is pregnant or currently breastfeeding or who plans to become pregnant.</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>
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<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>Germany</li> </ul>
<b>European country that will be involved in the trial (planned)</b>	<ul style="list-style-type: none"> <li>Austria</li> </ul>
<b>Estimated start date of recruitment</b>	August 2025

<b>6. Information for your doctor</b>			
<b>Clinicaltrials.gov identifier</b>	NCT06995573	<b>EUCT Number</b>	2024-518563-35-00
<b>Study contact information</b>	<a href="mailto:ptemel@neuroscios.com">ptemel@neuroscios.com</a>		
<b>Link to full text</b>	<a href="https://clinicaltrials.gov/study/NCT06995573">https://clinicaltrials.gov/study/NCT06995573</a> <a href="https://euclinicaltrials.eu/ctis-public/view/2024-518563-35-00">https://euclinicaltrials.eu/ctis-public/view/2024-518563-35-00</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.