

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

AT-24-03 STUDY

AT-24-03 study

1. Study Information	
Name of the study	Safety, tolerability and biomarker-based efficacy of NPI-001 (AT-001) in subjects with Alzheimer's disease
Study sponsor	Arctic Therapeutics ehf.
Disease	Mild Cognitive Impairment or mild dementia due to Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	NPI-001 (also known as AT-001)
Administration	Oral administration as tablet twice a day
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	<p>Participants will be selected by chance to receive one of the following options:</p> <ul style="list-style-type: none">• Oral tablet of NPI-001• Oral tablet 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). <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	
What are the researchers trying to find out?	<ul style="list-style-type: none">• The purpose of this study is to measure effects on plasma biomarkers and safety with NPI-001 compared with placebo in people with Mild Cognitive Impairment or mild Alzheimer's disease.
How long will the treatment last?	<ul style="list-style-type: none">• 12 months
What your involvement will entail?	<ul style="list-style-type: none">• During the study, participants will be asked to complete tests that will assess their memory, cognition, functional, behaviour, activities of daily living, suicide behaviour (CDR-SB, ADAS-Cog,

	<p>ADCS-ADL-MCI, MMSE, C-SSRS)</p> <ul style="list-style-type: none"> • Undergo brain scans (MRI, PET scans) • 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). <p>Further information on the procedures, tests and number of visits can be obtained from the study team.</p>
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<p>4. Who can participate in this study?</p>	
<p>Who can participate in the study?</p>	<p>To take part in the study, participants must:</p> <ul style="list-style-type: none"> • Be between 50 and 85 years old • Have a diagnosis of Mild Cognitive Impairment (MCI) or mild dementia due to Alzheimer’s disease according to the criteria of Jack 2024 • Have a score between 21 and 28 points in the MMSE test and 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 • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration.
<p>Who can’t participate in the study?</p>	<p>Exclusion criteria include:</p> <ul style="list-style-type: none"> • Moderate or severe dementia • A disease that may interfere with the safety or study assessments (e.g., vascular dementia, acute or subacute cerebral haemorrhage, large-vessel stroke, brain tumours,

	<p>inflammatory immunological, liver disease)</p> <ul style="list-style-type: none"> • Any alcohol or drug abuse within the past three months • Presence of suicidal ideation or behaviour. <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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5. Where and when will the study be conducted?	
European countries involved in the trial	<ul style="list-style-type: none"> • Iceland • Denmark
Estimated start date of recruitment	October 2025

6. Information for your doctor	
EUCT Number	2024-519497-39-00
Study contact information	<p>Ivar Hakonarson</p> <p>ivar@arctictherapeutics.com</p>
Link to full text	https://euclinicaltrials.eu/ctis-public/view/2024-519497-39-00

- ✓ The information contained in this document is based on information available on public registries (e.g. CTIS website) in November 2025.