Alzheimer Europe

Making dementia a priority:
changing perceptions, practice and policy.

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

SPPN-AD STUDY

Alzheimer Europe • R.C.S. LUXEMBOURG F2773 • 5 Heienhaff, L-1736 Senningerberg
Tel. +352 29 79 70 • Fax +352 29 79 72 • info@alzheimer-europe.org • www.alzheimer-europe.org

SPPN-AD study

1. Study Information	
Name of the study	A study to evaluate the Safety, tolerability, pharmacokinetics and Pharmacodynamics effects of NTRX-07 in subjects with Mild Cognitive Impairment or Mild to Moderate Alzheimer's disease
Study sponsor	Neurotherapia Inc.
Disease	Mild Cognitive Impairment or Mild to Moderate Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	NTRX-07
Administration	2 oral tablets once daily
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: • Oral tablets of NTRX-07 (45mg) • Oral tablets 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). 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 study will evaluate the safety and tolerability as assessed by the number of adverse events of NTRX-07 administered for 28 days in patients with Alzheimer's disease.
How long will the treatment last?	• The treatment will last 28 days • The participant study duration will be up to 7-10 weeks.
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their memory, cognition, functional, behaviour

	and activities of daily living (MMSE, ADAS-Cog, ADCS-ADL, iADLs) • Undergo brain scans (MRI) • Undergo electroencephalogram (EEG). This is a test that measures electrical activity in the brain • 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). Further information on the procedures, tests and 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 between 65 and 80 years old • Have a body weight within 55-110 kg • Have a score between 12-34 in the MMSE score and of 0.5-2.0 in the CDR scale. This would suggest that the person has an impairment in their memory that is at a mild to moderate stage • Confirmed medical documentation of Alzheimer's disease symptoms onset at age 60 or later • Have a score below 6 in the Geriatric Depression Score. This would mean that the person has no active depression • Live at home and have a study partner who has a sufficient contact with the participant (at least 3 times/week for 10

	hours), is willing to participate in study procedures throughout the study duration.
Who can't participate in the study?	Exclusion criteria include: • Diagnosis of a clinically relevant central nervous system disease other than Alzheimer's disease (e.g. Parkinson's disease, Huntington's disease, frontotemporal dementia, multi-infarct dementia, dementia with Lewy bodies, normal pressure hydrocephalus) • A disease that may interfere with the safety or study assessments (e.g., cardiovascular, respiratory, hepatic, renal, gastrointestinal, endocrinological, hematological, or neurological disorders, autoimmune disorders) • History of seizures, ischemic infarcts, subdural hematoma, hemorrhage, hydrocephalus, brain tumors) • HIV, hepatitis B or C virus • Reported regular use of known drugs of abuse within the past 3 years • Residence in a nursing home or assisted care facility with need for direct continuous medical care and nursing supervision. 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)	• Czechia • Hungary • Poland
Estimated start date of recruitment	April 2025

6. Information for your doctor	
EU CT Number	2024-517957-29-00
Study contact information	info@neurotherapia.com
Link to full text	https://euclinicaltrials.eu/ctis-public/view/2024-517957-29-00

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