Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ITI-1284-101 STUDY

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ITI-1284-101 study

1. Study Information	
Name of the study	A study to assess the efficacy and safety of ITI-1284 in the treatment of agitation associated with Alzheimer's dementia
Study sponsor	Intra-Cellular Therapies Inc.
Disease	Agitation associated with Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	ITI-1284
Administration	Oral tablet once daily (sublingual administration)
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 oral tablet of ITI-1284 (10mg or 20mg) • An 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). 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 efficacy, safety, and tolerability of ITI-1284 compared with placebo in the treatment of agitation associated with Alzheimer's dementia.
How long will the treatment last?	• The treatment period is 12 weeks • The treatment period will be followed by a safety follow-up period of 30 days which all participants will return for a safety follow-up visit approximately 30 days after the last dose of study drug.
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their behaviour (CMAI test) and overall mental health (CGI-S test).

	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 55 years old and older • Be able to provide consent before the initiation of any study-specific procedures • Have a body mass index (BMI) of 18–40 kg/m2 inclusive • Have a diagnosis of Alzheimer's disease according to the 2011 NIA-AA criteria • Have evidence of abnormal accumulation of amyloid in the brain (determined either through CSF examination (lumbar puncture) or with the use of an amyloid PET scan or confirmed by blood-based biomarker) • Meet all criteria for agitation according to the International Psychogeriatric Association (IPA) consensus definition • Has clinically meaningful agitation defined as a Neuropsychiatric Inventory-Agitation/Aggression (NPI-AA) domain total score of ≥ 4 • Have a score between 6 and 24 points in the MMSE test (a test about your general thinking skills).
Who can't participate in the study?	Exclusion criteria include: • Agitation symptoms attributable to concomitant medications, adverse environmental conditions, substance abuse, or active medical or psychiatric conditions

	• Diagnosis of psychiatric conditions such as schizophrenia, schizoaffective disorder, or other psychotic disorder that is not related to Alzheimer's dementia; bipolar disorder or major depressive disorder. • Risk for suicidal behaviour. 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	• Bulgaria • Croatia • Czechia • Romania • Serbia • Slovakia • Spain
Estimated start date of recruitment	July 2025

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT06651567	**EUCT number**	2024-514680-26-00
Study contact information	ITCIClinicalTrials@itci-inc.com		
Link to full text	https://clinicaltrials.gov/study/NCT06651567 https://euclinicaltrials.eu/ctis-public/view/2024-514680-26-00		

✓ The information contained in this document is based on information available on public registries (e.g. CTIS, clinicaltrials.gov websites) in January 2026.

✓ This document has been reviewed by a member of the European Dementia Carers Working Group.