

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

LESS-AD STUDY

LESS-AD study

1. Study Information	
Name of the study	Levetiracetam to prevent seizures in adults with Down syndrome and symptomatic Alzheimer's disease
Study sponsor	Fundació Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau
Disease	Down syndrome-associated Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	Levetiracetam
Administration	Oral administration (tablet twice daily)
Is the drug already on the market for another medical condition?	Yes - epilepsy medicine
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">• An oral administration of levetiracetam• An oral administration 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 the study is to examine the efficacy and safety of levetiracetam in people with Down syndrome and Alzheimer's disease. The objective is to evaluate whether levetiracetam can prevent epileptic seizures in people with Down syndrome that have symptoms of Alzheimer's disease. It will also analyse whether it can delay the neurodegeneration associated with this disease.
How long will the treatment last?	<ul style="list-style-type: none">• Almost 2 years (96 weeks)

<p>What your involvement will entail?</p>	<ul style="list-style-type: none"> • During the study, participants will be asked to complete tests that will assess their cognition, function and suicidal behaviour (a requirement for every clinical trial) • Complete some laboratory tests (e.g., blood test) and neurological examination including an electroencephalogram (EEG), which is a test that measures electrical activity in the brain • Undergo brain scan (MRI) at the beginning and at the end of 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 40 years and older • Be diagnosed with Down Syndrome (DS) • Have symptomatic Alzheimer's disease, based on change in cognition and neuropsychological evaluations' results • Have a study partner who has daily contact with the participant, willing to participate in study procedures throughout the study duration.
<p>Who cannot participate in the study?</p>	<p>Exclusion criteria include:</p> <ul style="list-style-type: none"> • Treatment with antiepileptic drugs, benzodiazepines, narcotics • A disease or medical condition that may interfere with the study assessments (i.e., moderate and/or severe untreated obstructive sleep apnea, clinically significant reduction in serum B12 or folate levels, clinically significant

	<p>abnormalities of thyroid function, stroke)</p> <ul style="list-style-type: none"> • Severe renal dysfunction • Concomitant or past history psychiatric or neurologic disorder other than those considered to be related to Alzheimer's disease (e.g., head injury with loss of consciousness, symptomatic stroke, Parkinson's disease, transient ischemic attacks) • Significant risk of suicide • Participation in another clinical trial within the past 3 months. <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 country involved in the trial	<ul style="list-style-type: none"> • Spain
Estimated start date of recruitment	January 2026

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT07234695	EU CT Number	2024-516148-24-00
Study contact information	María Carmona Iragui - +34 93 556 59 56 mcarmonai@santpau.cat		
Link to full text	https://clinicaltrials.gov/study/NCT07234695 https://euclinicaltrials.eu/ctis-public/view/2024-516148-24-00		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov, CTIS) in January 2026.
- ✓ This document has been reviewed by a member of the European Dementia Carers Working Group.
- ✓ This document has been reviewed by the sponsor running this trial.