Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

DIAN-TU-001 STUDY

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DIAN-TU-001 study

1. Study Information	
Name of the study	A study of potential disease modifying treatments in individuals at risk for or with a type of early onset Alzheimer's disease caused by a genetic mutation (DIAN-TU)
Study sponsor	Washington University School of Medicine
Disease	Early onset Alzheimer's disease
Phase	Phase II/III & Secondary prevention trial

2. Information about the drugs that will be tested in the study	
Name of drugs	This study tests different drugs. Current investigational products include lecanemab and E2814. Investigation with solanezumab is now closed. Investigation with gantenerumab is ongoing with an open label extension study, which enrolls participants of a previous clinical trial to continue to observe efficacy and measure long-term safety of gantenerumab.
Administration	Gantenerumab is administered via a subcutaneous injection (an injection under the skin) every four weeks. Lecanemab and E2814 are administered via an intravenous infusion (an injection into the vein).
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	**For the E2814 and lecanemab drugs:** Symptomatic participants will receive: • At Week 0, an intravenous infusion of lecanemab for the full treatment period • at Week 24, they will be selected by chance to receive an intravenous infusion of E2814 or placebo (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested with no active therapeutic effect) for the remainder of the treatment period.

	Neither the participant nor their doctor will know if the person is receiving E2814 or the placebo. Participants with normal cognition will receive: • At week 52, an intravenous infusion of E2814 or placebo for the full treatment period. Neither the participant nor their doctor will know if the person is receiving E2814 or the placebo. • At Week 24, they will receive an intravenous infusion of lecanemab for the remainder of the treatment period.

3. Information about participating in the trial	
What are the researchers trying to find out?	• The purpose of the study is to evaluate the safety, tolerability, biomarker, cognitive and clinical efficacy of investigational drugs in people who are known to have an Alzheimer's disease-causing mutation.
How long will the treatment last?	• Around 4 years
What your involvement will entail?	• During the study, participants will have to undergo brain scan (PET, MRI) and lumbar punctures (CSF) • Complete tests that will assess memory and cognition. Further information on the 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 18 and 80 years • Have a genetic mutation that causes Alzheimer's disease or are a family member with a dominantly inherited Alzheimer's disease (DIAD) mutation (e.g. APP, PSEN1, PSEN2) • Have a score of 0-1 in the Clinical Dementia Rating-Global Score (CDR). This would suggest that the person has no or

	mild impairment in their memory • Females of childbearing potential must agree to use effective contraception if partner is not sterile • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration.
Who cannot participate in the study?	Exclusion criteria include: • Evidence of significant abnormality on brain MRI scans • Drug or alcohol abuse or dependence within the past year • Presence of pacemakers, aneurysm clips, artificial heart valves, ear implants, or foreign metal objects in the eyes, skin, or body which would prevent MRI scan • History or presence of significant cardiovascular disease, liver/kidney disorders, infectious disease, immune disorder or uncontrolled hypertension • History of cancer within the last 5 years • Positive pregnancy test or plans to become pregnant during the trial period. 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	• France • Germany • Ireland • Italy

	• Netherlands • Spain • UK

6. Information for your doctor			
EudraCT Number	2013-000307-17	**Clinicaltrials.gov identifier**	NCT01760005
Study contact information	dianexr@wustl.edu		
Link to full text	https://classic.clinicaltrials.gov/ct2/show/NCT01760005		

✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on June 2024.