Alzheimer Europe

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

# CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

# DIAN-TU STUDY

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# DIAN-TU study

| 1. Study Information | |
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| **Name of the study** | Dominantly Inherited Alzheimer Network Trial: An opportunity to prevent dementia. A study of potential disease modifying treatments in individuals with a type of early onset Alzheimer's disease caused by a genetic mutation |
| **Study sponsor** | Washington University School of Medicine |
| **Disease** | Early onset Alzheimer's disease |
| **Phase** | Phase II/III & primary prevention trial |

| 2. Information about the drugs that will be tested in the study | |
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| **Name of drugs** | Investigational products including lecanemab and E2814 |
| **Administration** | The drugs (lecanemab and E2814) will be 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?** | Symptomatic participants will receive:<br>• an intravenous infusion of lecanemab for 24 weeks,<br>• then 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). Neither the participant nor their doctor will know if the person is receiving E2814 or the placebo.<br>• plus an intravenous infusion of lecanemab for the remainder of the treatment period<br><br>Participants with normal cognition will receive:<br>• an intravenous infusion of E2814 or placebo for one year. Neither the participant nor their doctor will know if the person is receiving E2814 or the placebo.<br>• and an intravenous infusion of lecanemab for the remainder of the treatment period. |

| 3. Information about participating in the trial | |
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| **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 products including lecanemab 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)<br><br>• Complete a test that will assess memory, orientation, judgment and problem solving, personal care and community affairs (this is a test called CDR-SB)<br><br>Further information on the number of visits can be obtained from the study team. |

| 4. Who can participate in this study? | |
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| **Who can participate in the study?** | To take part in the study, participants must:<br><br>• Have between 18 and 80 years old<br><br>• 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)<br><br>• Have a score of 0-1 in the Clinical Dementia Rating-Global Score (CDR). This would suggest that the person has no impairment in their memory or at a mild stage<br><br>• Be able to undergo brain scans (MRI, PET), Lumbar Puncture (LP), and complete all study related testing and evaluations<br><br>• Females of childbearing potential must agree to use effective contraception if partner is not sterile |

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| | • Adequate visual and auditory abilities to perform all aspects of the cognitive and functional assessments<br><br>• 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:<br><br>• A disease or medical condition that may interfere with the study assessments and will make the participant unsuitable for participation in or completion of the trial procedures (i.e. head trauma, seizure disorder, psychiatric disorders)<br><br>• At high risk for suicide<br><br>• Drug or alcohol abuse or dependence within the past year<br><br>• Evidence of significant abnormality on brain MRI scans<br><br>• 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<br><br>• History or presence of significant cardiovascular disease, liver/kidney disorders, infectious disease, immune disorder or uncontrolled hypertension<br><br>• History of cancer within the last 5 years<br><br>• Positive pregnancy test or plans to become pregnant during the trial period.<br><br>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? | |
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| **European countries involved in the trial (active)** | • Germany<br>• Italy<br>• Netherlands<br>• Spain<br>• UK |
| **European countries that will be involved in the trial (planned)** | • France<br>• Ireland |
| **Estimated start date of recruitment** | Early 2023 |

| 6. Information for your doctor | |
|---|---|
| **Clinicaltrials.gov identifier** | NCT05269394 |
| **Study contact information** | dianexr@wustl.edu |
| **Link to full text** | https://classic.clinicaltrials.gov/ct2/show/NCT05269394 |

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