Am I Eligible To Participate?

⇒ *Does your family have a Dominantly Inherited Alzheimer's Disease (DIAD) mutation (PSEN1, PSEN2, or APP) where symptoms started at less than 60 years of age in multiple generations of your family?*

⇒ *Are you cognitively normal **OR** do you have mild dementia?*

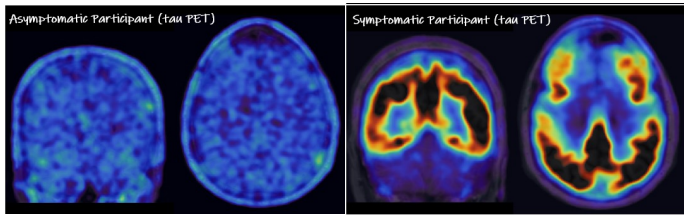
⇒ *Are you between the ages 18 to 80?*

⇒ *Do you have a family member or friend that can accompany you to visits and provide information about your medical history?*

⇒ *Are you willing to learn your mutation status in order to participate in a trial if you are receiving an active anti-amyloid therapy?*

*If you answered **YES to ALL** the above questions, you may be eligible to participate.*

*Please call us at: **1-844-DIANEXR (342-6397)***
or** email: **dianexr@wustl.edu



DIAN-TU
Dominantly Inherited Alzheimer Network Trials Unit

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Study: DIAN-TU-001
www.clinicaltrials.gov/ct2/show/NCT01760005

Please consider registering on our DIAN Expanded Registry website at:
dian.wustl.edu

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Dominantly Inherited Alzheimer's Disease

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What We Are Doing...

In 2012, the Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) at Washington University in St. Louis launched the first secondary prevention trial for Dominantly Inherited Alzheimer's Disease (DIAD) families. The initial drug arms tested in the trial were focused on amyloid-based therapies. The DIAN-TU is now planning to launch the Tau Next Generation (Tau NexGen) trial which will test three different drugs focused on therapies that target tau tangles.

The first tau drug to be tested is known as E2814 and is designed to target tau tangles; in addition, an active anti-amyloid drug called lecanemab (designed to target amyloid plaques) will also be administered. Both drugs are investigational and have been developed by Eisai Co., Ltd. This will be the first Alzheimer's prevention trial to target both tau tangles and amyloid plaques with two drugs at the same time. The research team continues to evaluate additional drugs to select with expectations to add then in 2022 and/or 2023, and plans to choose from two classes of tau drugs that act in different ways.

The trial's goal is to determine the safety, tolerability, and effectiveness of each drug. The DIAN-TU secondary prevention trial will determine if these medications can prevent, delay, or possibly even reverse Alzheimer's disease changes in the brain.

This study focuses on individuals who have a genetic likelihood to develop DIAD at a young age, typically in their 30s, 40s, or 50s. Although there are differences between DIAD and the more common age-associated sporadic Alzheimer's disease, the results of this study may have implications for future studies and treatments in sporadic Alzheimer's disease.

How You Can Help...

Are you or someone you know affected by DIAD? We are currently looking for participants with a parent or sibling who has been affected by a DIAD mutation. If you or someone you know fits this description, please contact us to find out more at: **Toll-free: 1-844-342-6397 or Visit the website at: dian.wustl.edu**

I Still Have Some Questions...

➡ ***If I am taking medications for memory impairment, can I continue taking them during the trial?*** ***Possibly****. Participants* ***may*** *remain on certain prescription medications but should check with your study team. You must be on a stable dose of an allowable medication before entering the study.*

➡ ***Can I participate in this trial if I do not want to find out my mutation status?*** ***No****. Participants that do not want to learn their mutation status will not be eligible to enroll into the E2814 arm of the trial because all participants will be receiving active anti-amyloid therapy. The mutation in your family must be known and participant's must be aware of the status for trial entry. If you would like to know your mutation status, the Expanded Registry can help set up genetic counseling and testing.*

➡ ***Do tau study drug treatment arms have a placebo group?*** ***Yes****. Tau study drug arms include placebo in order to determine the effectiveness and action of the study drug (E2814). Once a tau study drug is added to the trial, participants will have a* ***50% chance*** *of receiving active tau drug and a 50% chance of receiving placebo. All participants will receive the active anti-amyloid drug, lecanemab.*

➡ ***Who decides whether participants get the active drug or placebo?*** *A computer system randomly assigns participants to the active tau drug or placebo.*

➡ ***What if I can't get off work for study visits?*** *Where approved, there are trained home health nurses that can come to your home or other location before or after your work hours, and on weekends.*

➡ ***Can I screen now? Where can I find more information about the DIAN-TU trial and a study site?*** *If you would like more information on the trial, or to see if you may be eligible, please visit us at* ***dian.wustl.edu*** *or contact the DIAN Expanded Registry at* ***dianexr@wustl.edu*** *or call* ***1-844-DIANEXR (342-6397)****.*

What Happens Next?

A study coordinator will contact you to discuss the study schedule and qualification requirements. If you preliminarily qualify, the coordinator will send you a consent form with all the study details which they will review with you. If you are interested in joining the E2814 trial arm, you will sign the consent form to enroll.

The following does not represent all visits or study procedures but is a brief overview of the E2814 ***study schedule****:*

- ***Initial Screening*****:* *3-4 hours*
- ***Baseline & Annual Visits****:* ***3-4 day visit at a DIAN-TU site including the following:***
  - *Health History & Medication Review*
  - *Physical & Neurological Exam*
  - *Vital Signs, Urine & Blood Collection*
  - *Clinical & Cognitive Assessments*
  - *MRI, PET scans, and ECG*
  - *Lumbar Puncture*
  - *Study Drug Administration*
- ***Approximately Every Two (2) Weeks*:***
  - *Review of Health & Medication Changes*
  - *Vital Signs*
  - *Study Drug Administration*
- ***The below procedures will also be collected at the following time points:***
  - *Urine Pregnancy Test monthly, as applicable*
  - *Blood Collection every 3 months*
  - *MRI, Clinical, and Cognitive Assessments every 6 months, as applicable*

If you ***qualify and are interested****, a study coordinator will provide you with a full study schedule when discussing your potential for participation.*

**Visits may be performed in your home or other convenient location by a study nurse at a day/time that works for you.*