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?*

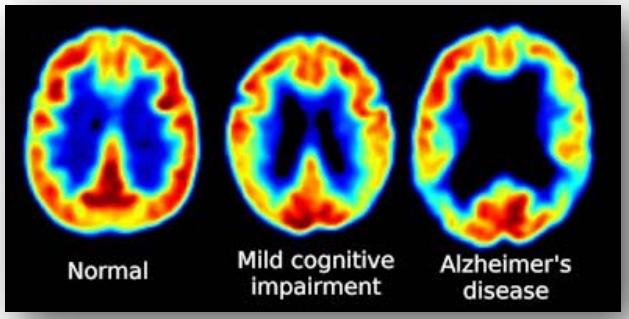
⇒ *Are you between the ages 18 to 80?*

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

⇒ *Do you plan to join one of the study drug treatment arms once it becomes available, if you qualify?*

*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's Network Trials Unit

Washington University in St. Louis
School of Medicine
Department of Neurology
Campus Box 8111
St. Louis, MO 63110

Phone: 844-DIANEXR (342-6397)
Fax: 314-747-7060
E-mail: dianexr@wustl.edu

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

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

DIAN TU
Dominantly Inherited Alzheimer Network
Trials Unit

Washington University in St. Louis
School of Medicine

DIAN TU
Dominantly Inherited Alzheimer Network
Trials Unit

Dominantly Inherited Alzheimer's Disease

Site Information:

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What We Are Doing...

In 2012, the Dominantly Inherited Alzheimer's Network Trials Unit (DIAN-TU) at Washington University in St. Louis launched the first prevention trial for Dominantly Inherited Alzheimer's Disease (DIAD) families. The Trials Unit continues to launch exciting new opportunities for DIAD families.

In August 2018, the DIAN-TU announced the plan to launch a US NIH funded Cognitive Run-In (CRI) period for participants to enroll when no study drug is available for immediate enrollment. This means that those individuals that are at risk or known carriers of a DIAD mutation have an opportunity for enrollment and contribution in advance of the next drug arm starting. Participation in CRI may help better identify the effectiveness of study drug arms once new drugs are added to the trial, and may help with learning results of the trial faster by decreasing the time it takes to enroll participants once a drug arm is open.

The trial's goal is to determine the safety, tolerability, and effectiveness of each drug. The DIAN-TU 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 that have 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

Template Version 5.0, 28 Nov 2018

I Still Have Some Questions...

- ***If I am taking medications for memory impairment, can I continue taking them during the trial?*** ***Yes***. *Participants **may** remain on prescription medications. However, they must be on a stable dose of the medication before entering the study.*
- ***Can I participate in this trial if I do not want to find out my mutation status?*** ***Yes!*** *You CAN participate in the trial if you do not want to know your mutation status. The mutation in your family must be known for trial entry, but individuals do not need to know their own mutation status. If, however, you would like to know your mutation status, the Expanded Registry can help set up genetic counseling and testing.*
- ***Do study drug treatment arms have a placebo group?*** ***Yes***. *Study drug treatment arms include placebo in order to determine the effectiveness and action of the study drug. Once a study drug is added to the trial, participants will have a **75% chance** of receiving active drug and a 25% chance of receiving placebo.*
- ***Who decides whether participants get the active drug or placebo?*** *A computer system randomly assigns participants to active drug or placebo. If you do not know your mutation status, and do not want to know, you can still participate. If you do not have a mutation, the computer will assign you to placebo.*
- ***What if I can't get off work for study visits?*** *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 sites?*** *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 Cognitive Run-In (CRI) period and eventually a study drug treatment arm, you will sign the consent form to enroll you in the trial. The following does not represent all visits or study procedures but is a brief overview of the **CRI study schedule**:*

- ***Initial Screening*:*** *3-4 hours*
- ***Entry & Annual Visits:*** ***2-3 day visit at a DIAN-TU site including the following:***
  - *Health History & Medication Review*
  - *Physical & Neurological Exam*
  - *Vital Signs, Urine & Blood Collection*
  - *Clinical & Cognitive (Memory and Thinking) Assessments*
  - *MRI and ECG*
  - *PET scan (for some participants)*
- ***Approximately Every Three (3) Months*:***
  - *Review of Health or Medication Changes*
  - *Cognitive Assessments in Person and/or on your smartphone*

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

**These visits may be performed in your home or other convenient location by a study nurse at a day/time that works for you. This usually includes before/after normal working hours and weekends.*