
Alzheimer's Disease Neuroimaging Initiative

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stopping the progression of Alzheimer's disease
ALZHEIMER'S DISEASE NEUROIMAGING STUDY

A landmark research study sponsored by
the National Institutes of Health

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Why is this study so important?

- This research may help us learn how to stop the progression of mild cognitive impairment (MCI) and Alzheimer's disease in future generations.
- Information from the study might, in the future, lead to new treatments or even a cure for Alzheimer's disease.



What is the goal of this study?

- The goal of this study is to determine whether imaging of the brain every six months can help predict the onset and monitor the progression of Alzheimer's disease.
- The imaging methods used will be Magnetic Resonance Imaging (MRI) and Positron Emission Tomography (PET) scans. In addition to neuroimaging, the study will test blood, and, for some participants, cerebrospinal fluid (from lumbar puncture) to determine if biomarkers can predict and monitor the disease.

Thank you!

Whether or not you will be participating in this research trial - thank you for your interest!

Without it, science could not move forward.

For more information, or to volunteer, contact:

ADEAR (Alzheimer's Disease Education & Referral Center)
at 800-438-4380, a service of the National Institute on Aging.

To find out about all participating research sites in Canada, contact
the Alzheimer Society of Canada at
support@alzheimer.ca or call 1-800-616-8816 ext. 239.

If they discover some other illness, would I be informed?

Yes. Any new information about your physical health will be shared with you.

Does a friend or relative have to accompany me at every visit?

No. For some visits, a friend or relative may be contacted by telephone if they cannot accompany you.

What about confidentiality?

Your privacy is very important. All collected data will be anonymous and major efforts will be made to keep your identity completely private.

Who is sponsoring this research study?

This research study is sponsored by the National Institutes of Health.

Where will this research study take place?

This study will take place at about 60 academic medical centers across the United States and Canada.

Are you eligible to participate?

Researchers are looking for persons who are between 55 and 90 years of age who:

- are in good general health with no memory problems, OR
- are in good general health but with memory problems or concerns, OR
- have a diagnosis of early Alzheimer's disease.



All volunteers must:

- be fluent in English or Spanish
- be willing and able to undergo the test procedures
- have a study partner - a friend or relative who can accompany the volunteer to all clinic visits or can answer questions over the phone

What is important for YOU?

- Your health will be closely monitored by a team of doctors and nurses.
- Any new information about your physical health will be shared with you.
- You will receive the latest information about the treatment of mild cognitive impairment and Alzheimer's disease.
- You will receive compensation for your time and costs incurred for travel, parking and meals.



What are the risks or side effects of MRI and PET scans?

The risks associated with MRIs and PET scans are minimal. They are considered safe and there has not been a report of an adverse event with this type of use. The risk of radiation exposure from the amount used is considered to be similar to other every day risks, such as driving a car. Some participants will be studied without PET scans.

What are the risks or side effects of a lumbar puncture?

Lumbar puncture (LP) is the medical procedure used to collect cerebrospinal fluid. When performed by an experienced doctor, LP is safe and involves minimal discomfort. There is no risk of paralysis. Testing cerebral spinal fluid is the only way to obtain important brain information.

You may experience minor pain, bruising or swelling of the skin where the needle is inserted - much as you might when giving blood. A post-LP headache can also occur. Less than 10% of those receiving an LP report a headache. Such headaches are usually mild and last 0-2 days. More severe headaches can occur in rare instances and these usually respond to treatment within a few hours. A very rare occurrence is infection from the tap itself; the risk for such infection is less than that of a regular blood draw.

If I develop Alzheimer's, will I get medication?

Should you develop Alzheimer's during the study, medication can be recommended and prescribed through discussions with your own physician. However, the cost for medication will have to be covered by you or your insurance.

Can I be involved in other clinical trials during this time?

No. Participation in another clinical trial would require you to withdraw from this study.

Are these open MRIs? I am claustrophobic.

There are no open MRIs. If you have a severe problem with claustrophobia, it is recommended that you not participate in this study. Otherwise, we will make every effort to make you as comfortable as possible.



FREQUENTLY ASKED QUESTIONS

How long does the study last?

- Two years if you have been diagnosed with early Alzheimer's disease
- Three years for all other participants

Will I receive recognition for my participation?

You will receive a Certificate of Appreciation for your important contribution to medical research.

How do I know if I can participate in the study?

Call the contact phone number (located on the last page of this brochure) and speak with someone to see if you fit the guidelines for those people needed to participate in the study. If so, the next step will be a screening visit (see below).

How often do I need to come to the clinic and what kind of medical exams will I receive during my visits?

First Visit - This first screening visit determines if you are eligible for the research study and helps to answer all your questions. At this visit you will receive a complete physical and neurological examination including an MRI. These measures will be used to assess change during the length of the study.

Second Visit - Also called the baseline visit, this visit will be scheduled very soon after the first screening. Some participants will undergo an MRI or PET scan and some will undergo the first lumbar puncture for collection of spinal fluid. Blood will be drawn and the first set of biomarkers (a measure of aging in cells, tissues and organs) will be established.

Third Visit - This visit will be scheduled approximately six months after the baseline visit. During this visit you will receive another complete neurological examination including an MRI. Some participants will also receive a PET scan.

Fourth Visit - This visit will be scheduled about six months after your third visit. Blood will be drawn and you will receive a complete physical and neurological examination including an MRI. Some participants will undergo their second -- and last -- lumbar puncture and some will also get a PET scan.

Fifth Visit - Instead of an actual visit, you will receive a follow-up phone call to you and/or your study partner about six months after the fourth visit. This is to see if all is well and if you have any questions or concerns.

Sixth Visit - This visit will be scheduled about six months after the follow-up phone call. For those who participate in the two-year study group - those with early Alzheimer's disease - it will be the final study visit. We will see you at the clinic for a complete physical and neurological examination including drawing of blood and an MRI. Some participants will also undergo a PET scan.

Seventh Visit - This will again be a follow-up phone call to you and/or your study partner about six months after the sixth visit. We will check if all is well with you and if you have any questions or concerns.

Eighth Visit - At this visit, about six months after your seventh visit, we will see you at the clinic one more time for a complete physical and neurological examination including drawing of blood and an MRI.



How long will each visit take?

About four hours.

**Will I be compensated for my time and expenses?
How much?**

You will receive compensation for your time and costs incurred for travel, parking and meals.

The study site where you participate determines the method and exact amount of compensation.
