

Clinical Trial – Imaging and Assessing Alzheimer’s Disease



Description: [18F]NAV4694 detects beta-amyloid in the brain, a protein that may contribute to Alzheimer’s disease.

If you or a family member are currently making end-of-life decisions, your participation in a national brain donation study could help researchers better understand Alzheimer’s disease.



Facts about Alzheimer’s Disease:

- ▶ In 2010, an estimated 35.6 million people worldwide were living with dementia.

WORLD HEALTH ORGANIZATION AND ALZHEIMER’S DISEASE INTERNATIONAL, (2012)

- ▶ Globally, 7.7 million new cases are expected each year. In the United States alone, AD is the fifth leading cause of death in Americans 65 years of age.

ALZHEIMER’S ASSOCIATION, (2012)

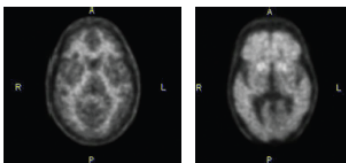
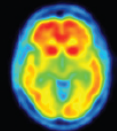
- ▶ Deaths from Alzheimer’s increased 68 percent between 2000 and 2010, while deaths from other major diseases decreased. Alzheimer’s disease is the only cause of death among the top 10 in America that cannot be prevented, cured or even slowed.

ALZHEIMER’S ASSOCIATION, (2014)

For more information, or to locate a participating clinical site near you, please visit:
www.clinicaltrials.gov
and search for NAV4-02

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Navidea Biopharmaceuticals has developed an investigational radioactive imaging compound, NAV4694. The drug binds to deposits of β -Amyloid plaques in the brain and emits a low level of radiation, which can be detected by a special camera called a PET scanner. The use of this drug may enable doctors to diagnose Alzheimer’s disease earlier and better.



Healthy volunteer (left) and Alzheimer’s subject (right) [18F]NAV4694 axial PET image at the level of the frontal lobes.

What makes NAV4694 different than other amyloid tracers?

NAV4694 is highly specific and attaches to beta-amyloid in the brain, with a low amount of attachment to white matter background, and creates a clean, clear-cut image.

NAV4694 is very sensitive and has the potential to detect low levels of β -amyloid in the brain which can lead to an earlier diagnosis, and can also be used to observe small changes of amyloid presence in the brain.

Who may qualify for this trial?

You may qualify for this study if you have a short life expectancy and agree to donate your brain after death. You must be at least 21 years of age and can either have Alzheimer’s disease or not.

What does this study involve?

- During participation you will receive:
- MRI (image of brain structure)
 - PET (image of β -Amyloid in brain)
 - Genetic Testing (hereditary risk associated with developing Alzheimer’s disease)
 - Cognitive Testing (Memory and Thinking)

Results of these tests will be shared with you and your family when possible.

After participation your family will receive the results of your brain autopsy.

FAQs about Brain Donation

Will my family get the results of my brain autopsy? Yes, results of your brain autopsy can be shared with your family if they choose to know them.

Will I need to change my funeral arrangements?

No, brain donation does not interfere with your choice of funeral, such as an open casket viewing. Donating your brain will not delay your family plans for a funeral either.

Will there be any cost to me or my family?

No, Navidea Biopharmaceuticals, the sponsor of this study, will cover all cost of your participation in this trial including brain autopsy.

Are there any risks?

Yes, your study doctor will be able to discuss all risks with you in more detail.

NAV4694 uses radiation. Radiation also occurs naturally in the environment and is used in treating and examining patients for medical reasons. The amount of radiation received from NAV4694 is the amount of radiation you absorb naturally from the environment over the course of 2 to 3 years.

In this study you may receive the study drug NAV4694 up to three times over 26 months.

