THE GOAL

REDUCING AMYLOID in ALZHEIMER'S DISEASE

ALZHEIMER'S DISEASE EDUCATION AND REFERRAL (ADEAR)

A service of the

National Institute on Aging

1-800-438-4380

http://www.nia.nih.gov/alzheimers

Conducted by the

Alzheimer's Disease Cooperative Study

ALZHEIMER'S DISEASE ADCS COOPERATIVE STUDY

WHY PARTICIPATE IN AN ALZHEIMER'S DISEASE CLINICAL RESEARCH STUDY?

- You ***CAN*** make a difference
- Your participation is critical for developing new treatments
- People like you are urgently needed to aid in finding new approaches for treatment, care and prevention of disease
- Drugs that are currently used to treat diseases were made possible by volunteers like you

WHAT ARE THE BENEFITS OF PARTICIPATING IN A CLINICAL RESEARCH STUDY?

- You can contribute to the understanding of a drug that may be a new treatment for Alzheimer's disease
- You will receive regular assessments by qualified health care professionals who specialize in Alzheimer's disease

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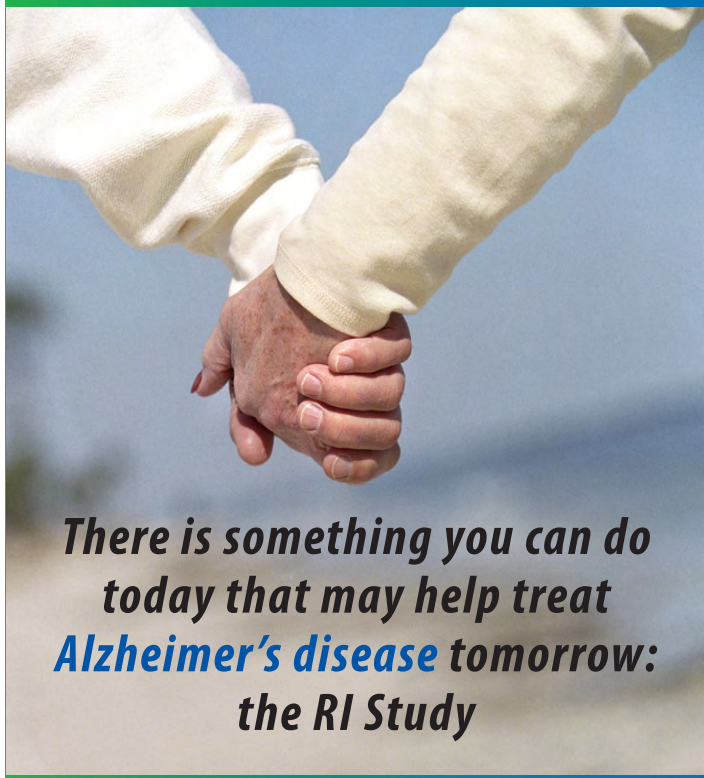

There is something you can do today that may help treat Alzheimer's disease tomorrow: the RI Study

A RESEARCH STUDY CONDUCTED BY THE ALZHEIMER'S DISEASE COOPERATIVE STUDY

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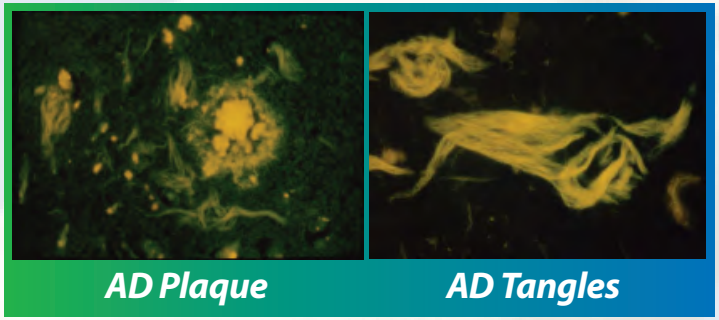

What is the goal of the study? To evaluate the effectiveness, safety and tolerability of the experimental drug compared to placebo.

Plaques and Tangles: Alzheimer's disease is caused by amyloid plaque deposits and tangles in the brain. These plaques and tangles lead to cognitive decline, memory loss and behavioral changes. Many proteins surround the amyloid plaques in Alzheimer's disease patients. One of the proteins, (**R**eceptor for **A**dvanced **G**lycation **E**ndpoints) called **RAGE** for short, binds to amyloid and may promote inflammation and lead to nerve cell damage.

Treatment at the Source: Researchers found that by inhibiting the RAGE protein, plaque formation could be reduced in animal models. The experimental drug was developed as a **RAGE inhibitor (RI)**. This is a novel pathway for trying to treat Alzheimer's disease. Some participants will be invited to volunteer for an important sub-study, which includes magnetic resonance imaging of the brain and a lumbar puncture, to examine cerebrospinal fluid for changes in amyloid beta protein and other markers.

How will the RI study work? The study will recruit nearly 400 volunteers at 40 U.S. research sites. Each participant will be evaluated in the clinic 12 times over the course of 21 months. Participants will be randomly assigned to one of three groups: two groups will receive different doses of the experimental drug and the third group will receive a placebo (an identical inactive pill).

What happens during the study visits? All participants undergo screening to determine if they are eligible to participate. If they are eligible for the study, various tests are performed such as electrocardiogram, blood pressures and pulse rates, blood and urine tests, body weight, physical examination, and cognitive testing.

What about my primary care provider?

- Regularly scheduled physician visits are not disrupted by the study protocols.
- Primary care physicians will be kept informed of your progress and laboratory results

What about my current medications and will there be any side effects with this new experimental drug? For detailed information, please contact the study site.

ELIGIBILITY CRITERIA:

- ***Are age 50 and older with probable mild to moderate Alzheimer's disease***
- ***Have not suffered from serious diseases within the past three months (contact study site for specific criteria)***
- ***Do not have Type 1 or Type 2 diabetes***
- ***Have a study partner who will accompany participant to each visit***
- ***Are able to travel to the clinic 12 times over 21 months***