Frequently Asked Questions

What are the risks or side effects of taking Resveratrol?

The risks associated with Resveratrol treatment may include abdominal pain, nausea, diarrhea, and kidney damage.

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

Lumbar Puncture, also called a spinal tap, is the medical procedure used to collect cerebrospinal fluid (CSF). When performed by an experienced doctor, LP is safe and involves minimal discomfort. There is no risk of paralysis. 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 those usually respond to treatment within a few hours. A very rare occurrence is infection or bleeding from the LP itself.

What are the risks or side effects of MRI scans?

The risks associated with MRI scans are minimal. They are considered safe and there has not been a report of an adverse event with this type of use. The risks of magnetic field exposure in the MRI scanner are minimal, and far less than other every-day risks such as driving a car. However, discomfort may occur as you will be asked to lie still on your back for a period of time.

FOR MORE INFORMATION PLEASE CONTACT:

Elaine Peskind, MD
Alzheimer's Disease Research Center
1660 S. Columbian Way
Seattle, WA 98108
(206) 764-2609 or
1(800) 317-5382

UNIVERSITY of WASHINGTON

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

ADRC Alzheimer's Disease Research Center

To learn the location of all participating research sites in the U.S., contact the Alzheimer's Disease Education and Referral Center (ADEAR), a service of the National Institute on Aging
1-800-438-4380
www.nia.nih.gov/alzheimers

This study is being conducted by the Alzheimer's Disease Cooperative Study (ADCS) through a grant from the National Institute on Aging, one of the National Institutes of Health (NIH).

ALZHEIMER'S DISEASE ADCS COOPERATIVE STUDY

Resveratrol
for Alzheimer's Disease

A Multi-Center, Double-blind, Placebo-Controlled Phase II Study to Evaluate the Impact of Biomarkers of Resveratrol in Participants With Mild-to-Moderate Alzheimer's Disease

UNIVERSITY of WASHINGTON

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

ADRC Alzheimer's Disease Research Center

Resveratrol
for Alzheimer's Disease

What is this study about?
The purpose of the Resveratrol research study is to evaluate the safety, tolerability and effectiveness of Resveratrol when given to people with Alzheimer's disease (AD). We will also be studying the effect of Resveratrol on cerebrospinal fluid (CSF) and blood biomarkers. The U.S. Food and Drug Administration (FDA) has not approved resveratrol for the treatment of AD or any other use. The use of resveratrol to treat AD is investigational and we do not know whether it can change the course of AD.

How will the study work?
In this study, people with AD will be given either Resveratrol or placebo (looks like the study drug but contains no active medication) for 12 months to determine whether daily Resveratrol therapy is beneficial in delaying or altering the deterioration of memory and daily functioning.

If you are eligible and agree to participate, you can continue the stable use of FDA-approved AD treatments (stable dose for at least three months prior to visiting the clinic). Participants cannot be enrolled in another clinical study during this time. Patient participation will last up to 12 months and will require up to 10 study visits. Some of these visits may be performed over multiple days. This is a double-blind, placebo-controlled study which means that neither you nor the research site will know if you are receiving Resveratrol or a placebo. You have a 50/50 chance of receiving either Resveratrol or the placebo.

Are you eligible to participate?
Researchers are looking for persons 50 years of age or older who:

- **Have a diagnosis of probable mild-to-moderate AD**
- **Are fluent in English**
- **Are willing and able to undergo clinic assessments, two lumbar punctures, three MRIs, and blood and urine tests**
- **Have a study partner to accompany the participant to ten study visits and have more than two days a week of contact with the participant**
- **Able to abstain from ingesting large quantities of Resveratrol-containing foods (including red wine). One to two glasses of red wine or red grape juice daily is acceptable; one serving of red grapes daily is also acceptable**
- **Able to abstain from ingesting herbal/natural preparations or dietary supplements containing Resveratrol. Resveratrol supplements are exclusionary**
- **Must not have taken an investigational drug within 2 months of Screening**

Where will this research study take place?
The Resveratrol Study is being conducted at about 26 research centers nationwide affiliated with the Alzheimer's Disease Cooperative Study.

How many people will be in the study?
The centers will enroll 120 participants (combined) with mild-to-moderate probable Alzheimer's disease

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.

What does placebo-controlled and double-blind mean?
Each study participant will be randomly assigned to the active treatment or placebo, with a 50/50 chance of receiving the active agent. Double-blind means that neither the patient nor the study staff will know who is receiving the active agent and who is not until the end of the study.

Can I continue taking my FDA-approved AD drugs?
Yes. This study allows continuation of stable use (at least three months) of all FDA-approved treatments for AD.

What about confidentiality?
Your privacy is very important. Major efforts will be made to keep your identity completely private.