Drug Study for Alzheimer’s Disease

The Byrd Alzheimer’s Disease Research Center at the University of South Florida is recruiting for a study. The goal of this project is to measure the effectiveness and safety of a drug called Filgrastim (Neupogen®) on improving thinking and memory in people with Alzheimer’s Disease.

If you have been diagnosed with mild to moderate Alzheimer’s Disease, you may be eligible to participate in this study. This brochure will give you some information about the study. If you are interested in participating or would like more information, please contact the Study Coordinator, Laura Murray, by phone at (813) 396-0619 or by e-mail at lmurray1@health.usf.edu

Purpose of the Study

We are studying people’s physical and mental response to a drug called Filgrastim (Neupogen®). Filgrastim is currently used safely in people who do not make enough white blood cells and people who wish to donate bone marrow. It has not
been studied in people with Alzheimer’s Disease, but in trials on mice with Alzheimer’s Disease the drug was found to increase learning. In humans, we believe Filgrastim may result in better thinking abilities, including memory and attention, and may decrease a certain amyloid protein in the brain which could halt or slow the disease process.

This is the very first study to see whether this drug helps thinking, memory, and attention in Alzheimer’s Disease. The other purpose of the study is to make sure the drug is safe before continuing to larger clinical trials.

Benefits

- **Every participant in the study will receive a course of Neupogen®** which may or may not improve thinking.

What we are asking you to do

The study is 14 weeks long and requires five injections under the skin over five days twice during the study. In order to monitor your safety, blood draws as well as neurological and physical exams will be routinely performed, as well as EKG measures and MRI scans. Participants will have scheduled visits for checkups and testing almost every week.

We will test for any changes in thinking using a number of neuropsychological tests. These tests will be performed five times during the study and will take about 90 minutes each time. There are no costs to you to participate.

Compensation for your time

- We will pay you $350.00 in order to help offset transportation costs incurred during the study.

Risks

- Filgrastrim has been used safely in humans, monkeys, and mice. However, possible side effects include bone pain, headache, fever, fatigue, and nausea. Tylenol or Advil is usually recommended to treat any side effects.

Requirements

All participants must meet the following conditions:

- Age 55 years or older.
- Diagnosis of mild to moderate Alzheimer’s Disease.
- Stable medical condition for past three months.
- Stable doses of all medications for past three months.
- Physically acceptable as confirmed by study doctors at the start of the study.
- Study partner able to come with you to all appointments.
- Fluent in English.

There are additional criteria for participating. To see if you qualify, please contact the study team.

If you want to participate

Contact Laura Murray at (813) 396-0691 or by e-mail at lmurray1@health.usf.edu

Study location

You may participate at the Johnnie Byrd Alzheimer’s Disease Research Center (ADRC). The ADRC is located on the USF campus just off Fletcher Avenue. The entrance to the ADRC is on the north end of the building (see the directions and map on this brochure).