



## Opportunities to Participate in Research at the Center for Cognitive Neurology

*Clinical studies and trials are the force behind the treatment, cure and prevention of any disease. Through the volunteerism of patients and those affected by an illness, knowledge is advanced, and a promise for a cure becomes more of a reality.*

### ***Hablamos Español***

#### **Memory Screening and Longitudinal Studies of Aging**

##### **Longitudinal Study of Normal Aging, Mild Cognitive Impairment (MCI) and Alzheimer's Disease**

Participants receive a comprehensive diagnostic evaluation and are re-evaluated every year. The goal is to improve early diagnosis and better understand the clinical course and causes of age-related cognitive decline and AD.

*For information, call Thee Oo at 212-263-8088; thee.oo@nyumc.org*

##### **MRI Progression Markers of Cognitive Decline in the Elderly**

This project investigates the relationship between plasma amyloid beta protein levels and brain vascular response to CO<sub>2</sub> (measured with MRI). Additional tests include brain structure measurement and CSF tau levels. We are currently enrolling normal participants and those who have mild cognitive impairment (MCI) over the age of 50. Participants will receive a comprehensive evaluation consisting of a neurological/physical examination, neuroimaging (MRI and ASL), memory testing, laboratory blood-work, ECG and lumbar puncture. Participants receive results and are compensated for their time and effort.

*For information, contact Emily Tanzi at 212-263-7563; emily.tanzi@nyumc.org*

##### **Are Sleep Disturbances a Risk Factor for Alzheimer's Disease?**

Our preliminary data show for the first time in normal elderly, that sleep disruption is associated with changes in cerebrospinal fluid (CSF) biomarkers, decreases in brain glucose metabolism (FDG-PET), brain atrophy, and progressive memory decline, all of which have been shown to be useful in predicting future dementia in late life. These findings raise the question as to whether Alzheimer's disease (AD) brain lesions cause sleep disruption in the elderly, or alternatively, if conditions that predispose one to sleep disruption, such as sleep apnea, acts as a risk factor for AD neurodegeneration. This study investigates these mechanistic hypotheses in cognitively normal elderly by examining the longitudinal associations between sleep disruption and cognitive decline, novel MR neuroimaging and CSF biomarkers for neurodegeneration; while our secondary goal is to launch a pilot treatment study to aid in interpreting the mechanistic hypotheses and to examine the effects of nasal continuous positive airway pressure (CPAP) on cognitive decline and neurodegeneration in participants with sleep apnea. Participants receive results and are compensated for their time.

*For information, contact Margaret Wohlleber at 212-263-7563 margaret.wohlleber@nyumc.org*

##### **Brain Sleep Clearance of Amyloid-Beta**

We are currently undertaking a 2 year NIH funded study of 60 subjects, in which two groups are being studied, to examine the relationship between disturbed sleep and the clearance of a the peptide associated with Alzheimer's disease (AD) known as amyloid-beta (A $\beta$ ) from the brain. Recent studies support the hypothesis that A $\beta$  dynamics in the brain are influenced by the sleep- wake cycle, with increases in the production of soluble A $\beta$  during wakefulness and decreases during slow wave sleep, also called deep sleep. These changes produce a consistent diurnal pattern in the cerebrospinal fluid (CSF) that has been documented in mouse models and in humans. The first group (age 55-75) will receive an 18F-florbetaben PET/MR scan to test for amyloid burden and then receive an overnight sleep study in a lab followed by a lumbar puncture (LP) for analysis of spinal fluid the morning after. The second group is comprised of normal middle age and elderly adults (age 30-75) with severe sleep apnea and good CPAP compliance. They will receive two nights of in lab sleep study. The first night consists of normal sleep with their habitual therapeutic CPAP. The second night includes a sleep disruption experiment in which CPAP pressure will be lowered to sub-therapeutic levels. A morning lumbar puncture will be performed after both nights. Participants receive results and are compensated for their time.

*For information, contact Clifton Lewis at 212-263-7563 clifton.lewis@nyumc.org*

### **Blood pressure, cerebral perfusion and cognitive performance in hypertension**

Hypertension (chronically high blood pressure) may lead to impaired blood delivery to the brain, which can cause brain shrinkage and cognitive decline. The NYU Center for Brain Health invites adults age 65-80, with or without hypertension, to participate in a research study. The purpose of this study is to examine the effects of one's current blood pressure on their brain, memory and thinking in the future. Your evaluation will include clinical exams, memory testing, bloodwork, ECG, carotid ultrasound, an MRI of the brain, and 24-hour ambulatory blood pressure monitoring. *For information, contact Catherine Randall at 212-263-7563; [catherine.randall@nyumc.org](mailto:catherine.randall@nyumc.org)*

### **Imaging Brain Inflammation using Positron Emission Tomography (PET)**

We hope to learn whether high blood pressure is associated with increased levels of brain inflammation using the technique of Positron Emission Tomography (PET). PET scanning measures brain activity by imaging small amounts of radioactivity emitted during scanning. The type of PET scan used in this study is designed to help researchers learn about inflammation in the brain. Inflammation is an important process that helps the body protect itself from infection and foreign substances, though inflammation can sometimes cause problems when it is excessive or inappropriate. In addition to the PET scan, study assessments may include MRI and memory testing. We are currently enrolling subjects with high blood pressure. Participants are compensated for their time and effort. *For information, contact Patrick Harvey at 212-263-7563; [patrick.harvey@nyumc.org](mailto:patrick.harvey@nyumc.org)*

### **Cognitive Detection of Preclinical Alzheimer's: Validation Using Biomarkers**

Detection of Alzheimer's disease during its early (or preclinical) stage has become very important for developing treatments to slow down or prevent the disease. Biomarkers, such as a positron emission tomography – computed tomography (PET-CT) scan for detecting amyloid in the brain, have been developed to detect Alzheimer-related brain pathology, but these methods are invasive, expensive or both. This study will confirm new computer memory and thinking tests (known as cognitive tasks) that may detect memory problems in the preclinical stage of Alzheimer's when there are no symptoms. Participants will perform the cognitive tasks and receive a PET-CT scan. Performance on the tasks will be compared to the scan results to discover if the tests can identify people who may have brain amyloid. You may join this study if you are between the ages of 60 to 85, inclusive and are in general good health. *For information, contact Sheila Mark at 212-263-7618, [Sheila.Mark@nyumc.org](mailto:Sheila.Mark@nyumc.org)*

### **Neurotrack Test Validation**

Detection of Alzheimer's disease during its early (preclinical) stage has become very important for developing treatments to slow down or prevent the disease. Biomarkers, such as the Magnetic Resonance Imaging (MRI) scan for detecting the shrinkage of brain regions, have been developed to detect Alzheimer-related brain pathology, but these methods are invasive, expensive or both. This study will validate new computer memory and thinking tests (known as cognitive tasks) that may detect memory problems in the preclinical stage of Alzheimer's when there are no symptoms. Participants will perform the cognitive tasks and receive an MRI scan. Performance on the cognitive tasks will be compared to the scan results to discover if the tests can evaluate people at risk for developing Alzheimer's. You may join this study if you are between the ages of 60 to 85, inclusive and are in general good health. *For information, contact Sheila Mark at 212-263-7618, [Sheila.Mark@nyumc.org](mailto:Sheila.Mark@nyumc.org)*  
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## **Opportunities to Participate in Clinical Trials at the Center for Cognitive Neurology**

To be eligible for a clinical trial, prospective participants should be on a stable medication dosage, present no other brain diseases (for example, Parkinson's or stroke), be cancer free for a minimum of two years, cardiovascular disease free for a minimum of six months, and have a study partner who can accompany them to clinic visits.

For information on Clinical Trials or to schedule a screening visit, please contact: Mrunalini (Ash) Gaikwad, Mohammed O. Sheikh or Anasztasia Ulysse; Clinical Trials numbers: 212-263-5708 / 5845 / 0771; Emails: [mrunaliniash.gaikwad@nyumc.org](mailto:mrunaliniash.gaikwad@nyumc.org), [mohammed.sheikh@nyumc.org](mailto:mohammed.sheikh@nyumc.org), [anasztasia.ulysse@nyumc.org](mailto:anasztasia.ulysse@nyumc.org)

## Studies for those with Mild Cognitive Impairment and/or Alzheimer's Disease

### **BACE ( $\beta$ -secretase) Inhibitor as Treatment for Prodromal Alzheimer's Disease**

We are offering a study to determine whether an oral, investigational medication will affect cognitive and behavioral functioning in individuals with prodromal Alzheimer's disease. The BACE inhibitor works by blocking the one of ways that beta amyloid, a protein linked to the cognitive and behavioral problems associated with Alzheimer's disease, is produced in the brain. There is hope that this drug will reduce amyloid plaque build-up in the brain, thus improving the negative symptoms and slowing the overall progression of the disease. We are **currently enrolling** individuals with **prodromal Alzheimer's disease** between the ages of 50 and 85. Participation lasts up to 2 years.

### **SUVN-502 as Treatment for Subject with Moderate Alzheimer's Disease currently treated with Donepezil Hydrochloride and Memantine Hydrochloride**

**\*Enrolling as of April 2016\***

### **Piromelatine as treatment for patients with mild dementia due to Alzheimer's Disease**

**\*Enrollment is expected to begin in Summer 2016\***

### **Aducanumab (BIIB037) as Treatment for Early Alzheimer's Disease (MCI)**

We are offering a study to determine whether the anti-amyloid monoclonal antibody Aducanumab, administered as an intravenous infusion once every four weeks would slow down the cognitive decline in individuals with Prodromal AD. To be eligible, individuals must be between the ages of 50 to 85 and have a positive amyloid PET Scan, which will be done as part of the study.

**\* Currently Enrolling\***

## Studies for the Prevention of Cognitive Impairment

### **Solanezumab to Prevent or Delay Onset of Alzheimer's Disease (the A4 Study)**

After promising findings in a recent study involving the anti-amyloid monoclonal antibody solanezumab, we will be running another intravenous infusion trial with solanezumab in **cognitively normal adults** who are believed to be at higher risk for developing Alzheimer's disease. This monoclonal antibody aims to reduce harmful amyloid build-up in the brain. Researchers hope that this drug will prevent or delay the onset of Alzheimer's disease. Infusions are every 4 weeks for about 3 years. **\*Currently Enrolling\***

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