

N.Y.C.A.R.E.

This insert is provided by New York Consortium for Alzheimer Research and Education (N.Y.C.A.R.E.) — a joint effort of the New York City Chapter of the Alzheimer's Association and the Education and Information Cores of the Alzheimer's Centers of Columbia-Presbyterian, Mount Sinai Medical Center and New York University School of Medicine — and funded by the National Institute on Aging.

Cholinesterase Inhibitors: Answers to frequently asked questions about their use

Cholinesterase inhibitors, such as Aricept, Exelon and Reminyl, have become standard treatment for the mild to moderate stages of Alzheimer's disease. Many people, however, still have questions about their effect on the illness, how long they should be used, and how much they cost. This article answers many of these questions.

Do cholinesterase inhibitors slow the progression of the disease?

None of the medications currently used to treat Alzheimer's disease have been shown to slow or halt the disease process. Cholinesterase inhibitors treat symptoms of the disease and have been proven in studies to have a positive effect, in some patients, on memory and thought processes, on functioning in everyday activities and on various aspects of behavior. (The treatment of behavioral symptoms, such as hallucinations and agitation, will be the subject of a future article.)

How can I tell that the medication is working?

Cholinesterase inhibitors generally produce modest benefits and it may be difficult for a person to determine whether the drug is effective in an individual case. The drugs' positive effects are most noticeable in large studies in which people taking the drug are compared to those on a placebo (a pill with no active ingredient). Since the disease continues to worsen even with the use of cholinesterase inhibitors, decline over time can be expected and does not necessarily indicate that the drug is not working.

Why would a doctor prescribe one drug rather than another?

Although all of the cholinesterase inhibitors work in a similar way, individuals may tolerate each of the drugs differently. A doctor will often consider the following when deciding which cholinesterase inhibitor to prescribe: a patient's tolerance of side effects, the convenience of the dosing schedule (such as once or twice a day), any medical conditions that could be affected by the medication, and any other medications a patient is taking that may not interact well with a particular cholinesterase inhibitor. Many people take the drug without experiencing side effects, however, common side effects include nausea, vomiting, diarrhea, weight loss, fatigue and sleep disturbances. Unless a person is having an adverse

reaction to one of the cholinesterase inhibitors, doctors generally do not switch patients to another drug.

Are cholinesterase inhibitors useful in treating mild cognitive impairment?

There is as yet no conclusive evidence proving the effectiveness of cholinesterase inhibitors in treating mild cognitive impairment (MCI). Since MCI is often a very early stage of Alzheimer's disease, studies are currently being conducted to determine the potential benefits of cholinesterase inhibitors in treating this condition. Currently, some physicians are prescribing cholinesterase inhibitors for people with MCI and insurance companies may cover the cost in some cases.

Are cholinesterase inhibitors useful in treating late stage Alzheimer's disease?

Cholinesterase inhibitors have been widely studied as treatments for mild to moderate Alzheimer's disease, but less is known about their effects in the later stages of the illness. While it is generally recommended that patients begin treatment as soon as possible after the diagnosis, there are no guidelines about when, during the long course of the illness, to stop treatment if the drug is well-tolerated. Many Alzheimer's patients continue to be treated with cholinesterase inhibitors well into the late stages of the illness. However, the cost of long-term treatment with these medications may become a consideration.

How expensive is treatment with a cholinesterase inhibitor?

Treatment with any of the three cholinesterase inhibitors in current use can be costly. Costs per month vary depending on dosage and the location of the pharmacy, from \$70.00 to approximately \$190.00. Insurance prescription plans cover these costs in most cases. Senior prescription plans are available from AARP and other organizations and may help reduce the price for those who do not have insurance. In addition, each of the companies that manufacture these drugs offers prescription assistance programs to individuals who do not have insurance and who meet certain financial requirements. For more information about prescription assistance programs, please see the following web sites: for Exelon, www.careplan.novartis.com; for Reminyl, www.us.reminyl.com/consumer/galantamine/financial.jsp; and for Aricept, www.pfizersharecard.com.

Columbia University Clinical Trials

Alzheimer's Disease Treatment in African Americans

A 12-week study to evaluate the safety and effectiveness of donepezil (Aricept) in African American patients, age 50 and older, diagnosed with mild to moderate Alzheimer's disease is currently being conducted. There must be no prior use of Aricept. Participants who complete the study will receive a 12-week supply of Aricept free of charge. For more information, please contact Audrey Bauzo at 212-305-2077.

Comparison of Alzheimer's Disease Medications Study

We are seeking men and women, age 60 and older, for a study to evaluate the effects of galantamine (Reminyl) and donepezil (Aricept) on sleep and attention and gastrointestinal (GI) tolerance in patients with mild to moderate Alzheimer's disease. To learn more, please call Ruth Tejada at 212-305-7661.

Treatment of Behavior Problems in Lewy Body Dementia and Alzheimer's Disease Study

Psychosis (hallucinations or delusions) and agitation often accompany dementia. Unfortunately, when dementia is complicated by parkinsonian symptoms (such as rigidity, slowed movements, shuffling gait), the drugs commonly used to treat behavioral problems can worsen these parkinsonian symptoms. We are seeking men and women, age 50 and older, with Alzheimer's disease or Dementia with Lewy Bodies who also have parkinsonian symptoms with psychosis and/or agitation to participate in a 12-week study to determine the effectiveness of the atypical antipsychotic quetiapine (Seroquel) and the cholinesterase inhibitor donepezil (Aricept) for the treatment of those behavior-related symptoms. For more information, please contact Ruth Tejada at 212-305-7661.

Cholesterol-Lowering Treatment and Alzheimer's Disease Study

Some evidence suggests a link between cholesterol and Alzheimer's disease-type changes in the brain. Other studies suggest lowering cholesterol may reduce these changes in the brain. We are seeking English and Spanish-speaking men and women, age 50 or older with mild to moderate Alzheimer's disease, to participate in a 12-15 month, placebo-controlled study to determine if the use of the cholesterol-lowering drug, simvastatin (Zocor), will be effective in slowing the progression of Alzheimer's disease. For more information, please contact Audrey Bauzo at 212-305-2077.

Antipsychotic Medication Treatment of Psychosis and Behavioral Dyscontrol in Alzheimer's Disease Study

Many people with Alzheimer's disease suffer from hallucinations, delusions, agitation, or aggression over the course of the illness. We aim to improve the quality of life of people with Alzheimer's disease, their families, and caregivers by studying the effectiveness of medications to treat these behavior-related symptoms. If interested, please contact Maddy Goodkind, Columbia University/NYSPI-RFMH at 212-543-5956.

Mood and Memory Study

A study examining the benefit of treatment for depression in people (age 50+) with combined depression and mild memory problems is currently being conducted. In those depressed patients whose memory problem persists, further treatment with medication to improve memory will be offered. If interested, please contact Jocelyn Cheng at 212-543-5067.

OTHER STUDIES

Memory Problems Study

We are seeking English and Spanish speaking participants, 50 years of age or older with memory problems to participate in a long-term follow-up study examining the clinical and brain imaging markers for the early diagnosis of Alzheimer's disease. If interested, please contact Dr. Matthias Tabert, Ph.D. at 212-543-5046.

Normal Aging and Memory Study

We are seeking men over the age of 70, in good health, without memory problems who wish to participate in a research study on understanding normal aging and memory, may earn \$10/hr at Columbia-Presbyterian Medical Center (Research Foundation For Mental Hygiene). No medication is prescribed. For more information, please call Maddy Goodkind at 212-543-5956. Spanish-speaking participants welcome.

Genetic Linkage Study

We are seeking Caribbean Hispanic families from the Dominican Republic for a study to identify genes that may increase the risk for AD. If you have at least two living family members diagnosed with AD, please call Vincent Santana at 877-636-5677 or Jennifer Williamson at 212-305-4655.

The Gift of Knowledge - Brain Donation Program

Brain donation allows valuable information to be obtained regarding normal aging and diseases that affect memory. This information may be useful towards the goal of developing more effective treatment strategies. If you or a family member wish to learn more about this program, please call Arlene Lawton, RN, at 212-305-9086.

Aging and Dementia Research Center The William and Sylvia Silberstein Institute for Aging and Dementia New York University School of Medicine

Current Studies

CLASP-AD [Cholesterol-Lowering Agent to Slow Progression of AD]:

Patients age 50 and older with mild to moderate Alzheimer's disease (AD) have an opportunity to participate in a study to evaluate whether an FDA approved cholesterol-lowering medication slows the progression of symptoms. Participants must not currently be receiving or requiring treatment to lower cholesterol. This is a 21-month trial. Concurrent use of other medications for the treatment of AD is allowed. Please contact the Clinical Trials Coordinator, Maria Vlassopoulos, at 212-263-5708 for more information.

Homocysteine:

Patients age 55 and older with mild to moderate Alzheimer's disease (AD) have an opportunity to participate in a study to evaluate whether a Vitamin B Complex can slow the clinical progression of the disease. A blood protein called homocysteine is elevated in AD, and people with high levels of this protein seem to have a greater risk of developing the disease. The purpose of this study is to test whether lowering levels of homocysteine with B vitamins can slow further decline in patients with AD. This is an 18-month trial. Sixty percent of the participants will randomly receive a Vitamin B Complex, while forty percent receive placebo (inactive substance). Concurrent use of other medications for the treatment of AD is allowed. For more information about this pharmaceutical study, please contact the Clinical Trials Coordinator, Maria Vlassopoulos at 212-263-5708.

COGNISHunt™ Study:

Ventricular shunts similar to those used in patients with hydrocephalus may also slow the course of Alzheimer's disease. We are beginning recruitment of mild - moderate severity Alzheimer's disease patients (ages 62 - 85) to receive shunt placement surgery. Patients selected for shunt surgery will be followed for 18 months: the first 9 months will be a randomized placebo controlled phase. The concomitant use of other Alzheimer's disease medications will be permitted during this study. For more information, please contact Jessica Lam at 212-263-5709.

An Innovative Psychosocial Intervention for Adult-Child Caregivers of Parents with Alzheimer's Disease:

A new study of an education and support intervention designed to reduce the stress, anxiety, and depression frequently experienced by people whose parents are in the moderate stage of Alzheimer's disease. The goal is to help caregivers provide a more stimulating environment for their parents and have a positive experience interacting with them and providing care. For information about this study, please call Cynthia Epstein 212-263-1056 or Alicia Pierzchala 212-263-7619.

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

Participants receive a comprehensive diagnostic evaluation and are re-evaluated every two years. The goal of this project is to improve early diagnosis and to better understand the clinical course and causes of age-related cognitive decline and Alzheimer's disease. For more information, please call Emma Shulman at 212-263-5756.

Biomarkers for Early Diagnosis of Alzheimer's Disease:

Normal elderly individuals with mild cognitive impairment (MCI) and people with Alzheimer's disease (AD) may volunteer to donate blood samples and cerebrospinal fluid (CSF). The goal is to validate biochemical indicators of AD that may lead to an early diagnostic test for this disorder. Reimbursement for time and effort will be provided. For further information, please contact Elissa Thorn at 212-263-7563.

Brain Donation Program:

Participants at the Silberstein Institute are eligible to participate in a free autopsy program that provides families with a definitive diagnosis and contributes to important research on the causes and treatment of brain aging and Alzheimer's disease. For further information, please contact Dr. Sadia Faiz at 212-263-5108.

Upcoming Studies

In the coming months there will be several new studies of interesting treatments for people with mild to moderate Alzheimer's disease and mild cognitive impairment (MCI). Participants will receive close medical follow-up by physicians and other healthcare professionals. Call 212-263-5708 for further information about future studies.

Alzheimer's Disease Research Center Mount Sinai School of Medicine

Homocysteine (HC) Study:

The purpose of this randomized, placebo-controlled study is to determine whether reduction of homocysteine levels with high dose folate/B6/B12 supplementation will slow the rate of cognitive decline in subjects with Alzheimer's disease.

Homocysteine is an amino acid (a building block of proteins) found in the bloodstream. Blood levels of homocysteine are elevated in AD, and these high levels may contribute to the disease. Patients over the age of 54 with Alzheimer's disease are eligible. All study medications are free of charge. For more information, please contact our research coordinator Jessica Stern at 212-241-8329. GCO# 91-208(11), MSSM IRB approved through 2/17/04

Guanfacine Study:

The goal of this 21-week study is to determine if treatment with Guanfacine, in combination with Aricept, Reminyl or Exelon will lessen cognitive impairment and behavioral disturbance associated with Alzheimer's disease more effectively than Aricept, Reminyl or Exelon alone. Patients are eligible for one year of free treatment upon completion of the study. For more information, please contact our ADRC research coordinator at 212-241-8329. GCO #84-119 MSSM IRB approved through 3/31/04

CATIE Study:

Many patients with Alzheimer's disease suffer from agitation, delusions, and hallucinations. In the hopes of improving quality of life for those with AD and their families, we are conducting a nine-month study to study the effectiveness of certain FDA-approved medications to treat those symptoms. Medication and medical care that are part of the study are provided at no cost. For more information, please contact our ADRC research coordinator at 212-241-8329. GCO #99-0052(2) MSSM IRB approved through 9/30/03

A Trial of an Insulin-Sensitivity Enhancing Agent to Improve Cognition in Alzheimer's Disease:

This study uses an insulin-regulating medication to enhance the activity of insulin degrading enzyme so that it can break down β -amyloid proteins. People with Alzheimer's disease cannot properly break down β -amyloid proteins, which accumulate to form plaques in the brain. This medication could interfere directly with the disease process by blocking the formation of plaques and hopefully prevent the development and progression of the disease. Patients with Alzheimer's disease are eligible. For more information, please contact our ADRC research coordinator at 212-241-8329. GCO #01-1223 MSSM IRB approved through 1/14/04

Statin Study:

We are seeking patients with Alzheimer's disease to participate in this multi-center, randomized, double-blind, placebo-controlled trial of simvastatin, a cholesterol-lowering drug. This study will test whether this drug can slow the progression

of symptoms in AD. For more information, please contact our ADRC research coordinator at 212-241-8329. GCO #91-208(10) MSSM IRB approved through 11/14/03

Protective/Risk Factors for Alzheimer's Disease in Healthy Adults:

This study aims to identify biological factors that might either predispose or protect individuals from developing Alzheimer's disease. The 2-3 hour interview would be completed at the subject's home. A small blood sample is drawn to allow investigators to examine possible protective factors. Participants will be compensated for their time. Men and women who are 85+ years old with no memory impairment or dementia will be eligible for the study. If interested, please contact the Family Studies Office at 718-584-9000, extension 2713. GCO #84-119 MSSM IRB approved through 3/31/04

MRI Study for AD Patients and Healthy Adults:

The aim of this study is to investigate the connection between brain functioning and cognitive testing. Subjects receive an MRI (Magnetic Resonance Imaging) test while answering some memory questions. Transportation is provided and participants will be compensated for their time. Men and women who are 70+ years old with a diagnosis of Alzheimer's disease, as well as those without memory problems will be eligible for the study. For more information, please contact our ADRC research coordinator at 212-241-8329. GCO #84-119 MSSM IRB approved through 3/31/04

Brain Tissue Donation Program:

The goal of this program is to improve existing treatments and to develop new treatments for AD, which is not possible without the generosity and altruism of individuals who partner with Mount Sinai by participating in our brain donation program. Therefore, men and women, with and without memory impairment are eligible to provide their "intent" to consent for this program. There are several benefits to participation and we have specially trained staff available to discuss these benefits, the donation process, and any related concerns that you and your family might have. For more information, please contact Maria Grotz, RN, NPP at 212-659-8812 or 917-952-2547. GCO #84-119 and #79-141 MSSM IRB approved through 3/31/04

Note: Spanish-speaking participants are welcome in all studies. All study participants receive reimbursement for any related expenses. Participants without AD receive monetary compensation for their time.

If you are interested in any of the above research studies, please contact the Alzheimer's Disease Research Center at 212-241-8329. Mount Sinai also has satellite clinics specializing in AD and other Memory Disorders located at:

Elmhurst Hospital in Queens: 718-334-3983

Bronx VA Medical Center: 718-584-9000 ext. 5199

Phelps Memorial Hospital in Westchester: 914-366-3669