

Drug Gives New Hope in Treating Symptoms of Severe Alzheimer's

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Toronto, ON (July 30, 2007) - A renowned neurology researcher at Sunnybrook has led an international community study that shows an existing drug can help safely treat symptoms in more severe stages of Alzheimer's disease (A.D.).

"This new research provides a ray of hope that we can continue treatment of symptoms for patients in the community even in the later stages of the disease," says Dr. Sandra Black, principal investigator of the study, neurologist and researcher at Sunnybrook Health Sciences Centre. "Until now, cholinesterase inhibitor drugs have been used to treat mild to moderate stages of the disease. Now we know they can help preserve cognition and global functioning in severe-stage patients, providing support for continuing use of these drugs in the more severe stage. It is important to keep in mind, however, that this class of drugs treat the symptoms, but does not stop the progression of the actual disease."

During a six-month trial period, overall cognitive function of treated patients stabilized. Memory, language, attention, and ability to sequence (hand) movements actually improved. They were less apathetic, and engaged more in conversation.

"The improvement in cognition could mean remembering a child's name, being able to speak more, or expressing more emotional connection," says Dr. Black, who is also a professor in the Division of Neurology at University of Toronto. "While the disease continues to move ahead, the possibility of preserving some of these abilities can be meaningful to loved ones and to the patient, and it may also help to keep patients at home longer. It is important to help in any way we can for people in the later stages of the disease."

The study, published in the July 31, 2007 issue of *Neurology*, involved 343 participants and took place over six-months at 98 clinics located throughout Canada, the United States, the United Kingdom, France and Australia. "The trial enrolled patients still living in the community," says Dr. Black. "These patients are significantly impaired, highly dependent on others, are usually disoriented in space and time, and in the very late stage may be almost mute."

In this double-blinded, placebo-controlled trial, patients were randomized to the drug donepezil or placebo, and underwent cognitive tests throughout the study. Donepezil was significantly better than placebo on the Severe Impairment Battery (SIB), a measure of cognitive impairment, and on a global impression of change. The drug was well tolerated overall, with the most common side effects being diarrhea and nausea, both of which were generally mild or moderate and consistent with known gastrointestinal side effects of such drugs.

"This research provides evidence drug treatment may still be helpful for late stage Alzheimer patients living in the community," says Dr. Black. As a result, the Food and Drug Administration (FDA) in the U.S., and more recently Health Canada, have approved the drug for "labeled use" in patients with severe stage A.D.

While similar studies have been carried out in nursing homes with professional caregivers, this is the first time such a study was carried out in a community setting.

There are currently three cholinesterase inhibitor drugs on the market, one of them being donepezil. These drugs inhibit or block off the enzyme in the brain that breaks down the neurotransmitter, which is vital for transmission of nerve impulses. The drugs therefore chemically restore transmitter function, helping to relieve the disease's symptoms. Another drug, memantine, which blocks excessive amounts of a different transmitter, glutamate, is also marketed for moderate to severe stage A.D.

The study was co-led by Dr. R. Doody, a U.S. neurologist, and sponsored by Eisai Inc. and Pfizer Inc.

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