

Alzheimer's Disease Clinical Trials Program

A collaboration between:

Acadia Hospital Geriatric Neuropsychiatry Program and EMMC Clinical Research Center

Dr. Clifford Singer, Principal investigator of the *Alzheimer's Disease Clinical Trials Program* and his team at Acadia Hospital and EMMC Clinical Research Center are conducting clinical trials for people with Alzheimer's disease (AD) or those at risk of developing AD. The clinical studies being done at Acadia Hospital include experimental treatment options for various stages of AD, including people at risk but who do not yet have memory impairment.

Open studies as of January 2018:

For people with either Mild Cognitive Impairment or already showing signs of Mild to Moderate Dementia:

1. A Randomized, Delayed-Start Study of LY3314814 in Mild Alzheimer's Disease Dementia "The DAYBREAK Study"

The main purpose of this study is to evaluate the efficacy of the study drug known as LY3314814 in 78 weeks with participants that have mild Alzheimer's disease (AD) dementia. LY3314814 is a brain-permeable inhibitor of human Beta-site amyloid precursor protein-cleaving enzyme 1 (BACE1)Beta-secretase. It is being developed for the modification of the clinical course of Alzheimer's disease (AD) by slowing disease progression in patients diagnosed with early Alzheimer's Dementia (which is defined as mild cognitive impairment (MCI) due to AD and mild dementia of AD type).

For more information, contact: Krysta Anderson at 207-973-4263 or keanderson@emhs.org

2. A Phase 2A Multicenter, Randomized, Double-Blind, Parallel Group, 26-Week, Placebo-Controlled Study of 50 mg and 100 mg of SUVN-502 in Subjects with Moderate Alzheimer's Disease Currently Treated with Donepezil Hydrochloride and Memantine Hydrochloride

This study is designed to test the hypothesis that SUVN-502 improves the cognitive status of Alzheimer's disease subjects who are currently being treated with donepezil HCl and memantine HCl.

For more information, contact: Kathleen Chamberlain at 207-973-7726 or kmchamberlain@emhs.org

4. Long-Term Nicotine Treatment of Mild Cognitive Impairment. (MIND)

To test whether daily transdermal nicotine will produce sustained cognitive, clinical, and functional benefits for patients with MCI in a 2-year multi-center clinical trial. People with vascular dementia, Parkinson's disease dementia and Lewy body disease dementia are also eligible.

For more information, contact: Kathleen Chamberlain at 207-973-7726 or kmchamberlain@emhs.org

5. Relapse Prevention Study of Pimavanserin in Dementia-related Psychosis

The purpose of this study is to evaluate the efficacy of pimavanserin by comparing pimavanserin with placebo in preventing a relapse of psychotic symptoms in subjects with dementia-related psychosis and who were stabilized after 12 weeks of open label pimavanserin treatment. Pimavanserin has been shown to improve delusions and hallucinations in persons with Parkinson's disease with fewer neurologic side effects than other medications and is therefore being studied in other types of dementia.

For more information, contact: Kathleen Chamberlain at 207-973-7726 or kmchamberlain@emhs.org

6. A phase III safety and efficacy study of ALZT-OP1 in subjects with evidence of early Alzheimer's disease

This is a global Phase III, randomized, double-blinded, placebo-controlled study for subjects with evidence of early AD. The protocol is designed to determine whether ALZT-OP1 combination treatment (ALZT-OP1a + ALZT-OP1b) will slow down, arrests, or reverse cognitive and functional decline, in subjects with evidence of early stage Alzheimer's disease (AD).

For more information, contact: Nina Vekima at 207-973-7224 or nvekima@emhs.org

For people with Normal Memory for their age but at risk for Alzheimer's Disease because of a family history or age:

1. A Phase 2b/3 Randomized, Double-blind, Placebo-Controlled, Parallel Group, Multicenter Study Investigating the Efficacy and Safety of JNJ-54861911 in Subjects who are Asymptomatic At Risk for Developing Alzheimer's Dementia: "The EARLY Study"

The primary objective of this study is to determine whether treatment with JNJ-54861911 slows cognitive decline compared with placebo treatment, in amyloid positive subjects who are asymptomatic and at risk for developing Alzheimer's dementia.

For more information, contact: Kristie Miner at 207-973-6986 or kminer@emhs.org or visit www.earlytrial.com

See www.clinicaltrials.gov or call for more information.

