FAU site for first US clinical trial for Lewy Body dementia

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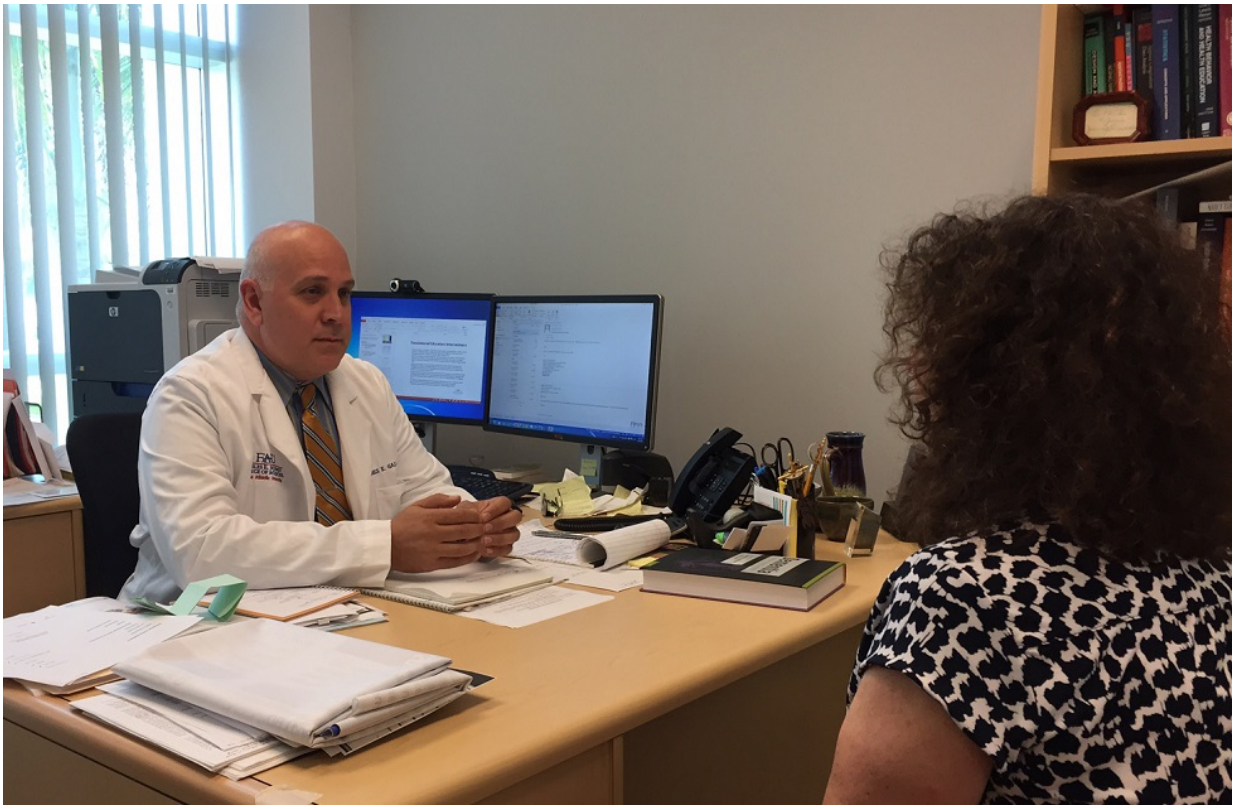

The South Florida clinical trial is directed by one of the world's leading neuroscientists and an expert on LBD, James E. Galvin, M.D., M.P.H., a professor of clinical biomedical science in FAU's College of Medicine, a professor in FAU's Christine E. Lynn College of Nursing, and medical director of FAU's Louis and Anne Green Memory and Wellness Center. Credit: Florida Atlantic University

Florida Atlantic University's Charles E. Schmidt College of Medicine is spearheading the South Florida site for the first U.S. clinical trial for Lewy body dementia (LBD), the second-most common dementia after Alzheimer's disease. The HEADWAY-DLB is a phase 2b multi-center, double-blind, placebo-controlled study to evaluate an investigational medicine, RVT-101, for dementia with Lewy bodies.

Currently, there are no medications available to specifically treat LBD, and patients are typically treated with medications for Alzheimer's.

The six-month study will enroll approximately 240 patients nationally to evaluate the safety and efficacy of RVT-101, a tablet that works by raising levels of acetylcholine, a vital chemical in the brain that helps with cognition and performing daily activities. Deficits in acetylcholine are a prominent feature of dementia with Lewy bodies.

Because symptoms of LBD mimic other diseases like Parkinson's and Alzheimer's, it is very difficult to diagnose often taking up to 18 months, with patients seeing a number of physicians over multiple visits. Patients, who are often misdiagnosed, are given medications for psychiatric disorders, Alzheimer's and Parkinson's. The only way to confirm whether someone has LBD is with a post-mortem brain autopsy.

The late Robin Williams had this form of dementia as did legendary NHL coach Alger Joseph "Radar" Arbour, legendary radio personality Casey Kasem, and most recently, Hall of Famer Gerald Eugene "Jerry" Sloane, former NBA player and head coach of the Utah Jazz.

Dementia with Lewy bodies is a progressive type of dementia that affects more than 1 million people in the U.S. LBD is characterized by fluctuations in cognition, particularly in alertness and attention, and can make depression worse. Many LBD patients also have visual hallucinations and REM sleep behavior disorder. LBD is characterized

by the buildup of abnormal protein clusters (known as "Lewy bodies") within the brain.

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Galvin developed the "Lewy Body Composite Risk Score" (LBCRS) to quickly and effectively diagnose LBD and Parkinson's disease dementia (PDD) in about three minutes. The LBCRS is a brief rating scale that can be completed by a clinician to assess clinical signs and symptoms highly associated with the pathology of this disease.

"Diagnosing dementia with Lewy bodies early is critical, and with this important tool, a clinician can assess whether the patient has bradykinesia, rigidity, postural instability, or rest tremor without having to grade each extremity," said Galvin. "We are hopeful that we also will be able to assist patients who have dementia with Lewy bodies with a medication that is designed to address their specific needs and condition."

Galvin has been working to improve clinical detections by combining biomarkers including high density EEG, functional and structural MRI, PET scans and CSF biomarkers to characterize and differentiate LBD from healthy aging and other neurodegenerative diseases.

Galvin has led efforts to develop a number of dementia screening tools, including the Quick Dementia Rating System (QDRS), AD8, a brief informant interview to translate research findings to community settings. He has done cross-cultural validation of dementia screening methods in comparison with Gold Standard clinical evaluations and biomarker

assays. His team also has developed sophisticated statistical models to explore transition points in clinical, cognitive, functional, behavioral and biological markers of disease in healthy aging, mild cognitive impairment, Alzheimer disease, and Parkinson's disease.

Provided by Florida Atlantic University