Pilot trial of dronabinol adjunctive treatment of agitation in Alzheimers disease (AD)

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Question
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Related
Institution

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Contact information of lead PI
Country

USA

Title of project or programme

Pilot trial of dronabinol adjunctive treatment of agitation in Alzheimers disease (AD)

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NIH (NIA)

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1

The project/programme is most relevant to:

Alzheimer's disease & other dementias

Keywords

Acquired Cognitive Impairment... Aging... Alzheimer's Disease... Alzheimer's Disease including Alzheimer's Disease Related Dementias (AD/ADRD)... Behavioral and Social Science... Brain Disorders... Cannabinoid Research... Clinical Research... Clinical Research - Extramural...

Clinical Trials and Supportive Activities... Dementia... Effectiveness Research... Mental Health... Neurodegenerative... Neurosciences... Therapeutic Cannabinoid Research... Translational Research

Research Abstract
? DESCRIPTION (provided by applicant): Background: Alzheimer's disease (AD) is the commonest neurodegenerative disease of aging affecting an estimated 5 million persons in the U.S. and anticipated to triple by 2030. The symptoms are not only cognitive but emotional, and neuropsychiatric symptoms such as agitation, depression, and apathy are highly prevalent in AD and a major cause of burden to patients, families, and society. Agitation in AD (Agit-AD) is a particularly acute cause of caregiver burden, and current treatments for Agit-AD are not highly effective particularly for severely impaired patients. Thus, there is a need for improved treatments for Agit-AD. Specific aim 1: To evaluate the efficacy of 3 weeks dronabinol vs. placebo adjunctive treatment in 80 inpatients with severe Agit-AD. Hypothesis 1: Compared to placebo, dronabinol treatment will be associated with a greater reduction in symptoms of agitation as measured by the PAS and the agitation domain of the Neuropsychiatric Inventory-Clinician Version (NPI-C). Specific Aim 2: To evaluate the safety profile of dronabinol vs. placebo adjunctive treatment in 80 inpatients with severe Agit-AD. Hypothesis 2: Dronabinol treatment will be well tolerated with no more than mild adverse events (AEs). Public Health Significance: There is a great need for better interventions that target Agit-AD, which is a major source of caregiver burden and stress, particularly for moderate to severe agitation. This could open the door to ""repurposing"" dronabinol as a novel and safe treatment for Agit-AD with significant public health impact. Innovation: 1) first North American RCT of dronabinol for Agit-AD; 2) first RCT of dronabinol at 10 mg dose. Current trials in the field limit the dose to 4-6 mg daily and underdosing should be assiduously avoided in an early phase trial to avoid missing potential benefit; 3) first multi-site RCT of dronabinol for Agit-AD. Method: We propose a three - week placebo-controlled, double-blind, randomized clinical trial of 10 mg daily dronabinol as an adjunct to currently used psychotropic medications in 80 inpatients with severe Agit-AD. The trial will be undertaken at two clinical research sites (Johns Hopkins and McLean Hospitals) and use the Pittsburgh Agitation Scale as primary outcome, with additional agitation scales (Cohen-Mansfield Agitation Inventory and Neuropsychiatry Inventory – Clinican Version), cognitive measures (MiniMental State Exam), and sleep and drug intoxication measures as secondary outcomes. Data analyses will be by intent-to-treat. Participants, clinical staff, and raters will b blinded to treatment assignment. Expected Results: if we observe benefit from dronabinol this could lead to a definitive hypothesis-testing phase 3 trial with potential impacts on public health If we observe no benefit at this relatively high dronabinol dose this will likely not lead to furthr development of this intervention. Impact on other research areas: agitation is common in other neuropsychiatric diseases and dronabinol might be helpful in those as well, including Parkinsons', Huntingtons', and frontotemporal dementia.

Lay Summary
PUBLIC HEALTH RELEVANCE: Patients with Alzheimer's disease (AD) often have severe agitation, and we have preliminary data suggesting that dronabinol (a medication derived from the active ingredient in marijuana and FDA-approved for severe lack of appetite) may also be safe and helpful in treating persons with AD and agitation. We propose to test the effect of three weeks dronabinol treatment in 80 patients at Johns Hopkins and McLean Hospitals, assessing primarily whether dronabinol helps agitation but also importantly assessing its safety.

Further information available at:

Types:
Investments > €500k

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United States of America

Diseases:
Alzheimer's disease & other dementias

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