

Study to Examine Possible Effects of Cannabis Compound for Common Movement Disorder

Phase I/II clinical trial will be first of its kind to explore cannabis as a potential treatment option for essential tremor

September 18, 2018 | Gabrielle Johnston, MPH

Researchers at University of California School of Medicine are preparing to launch a novel clinical trial to examine the safety, efficacy and pharmacological properties of cannabis as a potential treatment for adults with essential tremor (ET). Currently, ET is treated using repurposed medications originally developed for high blood pressure or seizures. Surgery is another option.

Scheduled for early 2019, the phase I/II trial will assess efficacy and tolerability of an oral cannabis formulation comprised of cannabidiol (CBD) and low-dose tetrahydrocannabinol (THC). Researchers say it will be the first time this combination has been studied for treatment of ET.

“This study will provide key insights,” said [Fatta Nahab, MD](#), neurologist at UC San Diego Health and associate professor of neurosciences at UC San Diego School of Medicine. “If found to be safe and effective, cannabis would not only serve as an exciting new addition to the limited treatment options currently available for patients with ET, but it might also provide scientists with new insights on essential tremor.”

CBD is a major chemical compound found in cannabis. It does not produce the effects of feeling “high,” which are caused by THC. Both CBD and THC are two of more than 100 cannabinoids in cannabis and both interact with the body’s endocannabinoid system, a network of neurotransmitters that regulate diverse physiological and cognitive processes and response to stress.

In collaboration with UC San Diego School of Medicine’s Center for Medicinal Cannabis Research (CMCR), the study will involve a team of researchers evaluating the compound’s various properties, including its pharmacology in the body.

“CMCR is excited to collaborate with Dr. Nahab on a study for a difficult-to-treat condition for which cannabinoids may provide a new therapeutic avenue,” said Igor Grant, MD, CMCR director and chair of the Department of Psychiatry at UC San Diego School of Medicine. “This work expands CMCR’s commitment to develop an evidence-based approach in the area of cannabinoid therapeutics. The oral combination of CBD and THC is the first-of-its-kind to be studied and is especially interesting to CMCR.”

The double-blind, placebo-control, cross-over clinical trial will enroll 16 adult participants who have been diagnosed with ET by a movement disorder neurologist. All study participants will be gradually administered an oral cannabis formulation with a 20:1 ratio of CBD to THC. After completing a two-week period at the maximum target dose, participants will taper off, followed by a washout period before crossing over to the alternate study arm.

Nahab estimated the trial will take approximately one year to complete.

Essential tremor is a nervous system disorder characterized by involuntary, rhythmic shaking of any part of the body, most notably the hands. It affects an estimated 10 million American adults, and is often confused with Parkinson's disease. The condition can make routine tasks, such as drinking water or tying shoelaces, difficult. ET usually worsens over time and often becomes a common cause of embarrassment, social withdrawal, disability and loss of occupation for those with the disorder.

Cannabis is a Schedule 1 drug, as defined by the Drug Enforcement Administration (DEA), and availability for research purposes is strictly limited. The capsule cannabinoid formulation for this study will be provided by Tilray, a Canada-based cannabis company specializing in the research, cultivation, production and global distribution of cannabis and cannabinoids. Tilray received approval from the DEA to import this medical cannabis-derived study drug into the United States from Canada. Tilray currently serves tens of thousands of patients in eleven countries spanning five continents.

To learn more about essential tremor, visit the International Essential Tremor Foundation at www.essentialtremor.org/