

Marijuana derivative reduces seizures in people with treatment-resistant epilepsy

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Generalized 3 Hz spike and wave discharges in a child with childhood absence epilepsy. Credit: Wikipedia.

Cannabidiol (CBD), a medical marijuana derivative, was effective in reducing seizure frequency and well-tolerated and safe for most children and young adults enrolled in a year-long study led by epilepsy specialists at NYU Langone Medical Center.

These latest findings provide the first estimates of safety, tolerability and efficacy of prescription CBD in children and adults with severe, highly treatment-resistant epilepsy. Led by Orrin Devinsky, MD, professor of neurology, neurosurgery, and psychiatry and director of the Comprehensive Epilepsy Center at NYU Langone, the study is published in the December 23 issue of *Lancet Neurology*. While early findings have been released at medical meetings—including the 2015 American Academy of Neurology conference—these are the first findings from the trial to be published in a peer-reviewed journal.

The study took place at 11 epilepsy centers across the country. Patients were given the oral CBD treatment Epidiolex over a 12-week treatment period. Results showed a median 36.5 percent reduction in monthly motor seizures, with the median monthly frequency of motor seizures falling from 30 motor seizures a month at the study's start to 15.8 over the 12 weeks. Equally important, CBD was shown to have a sufficient safety profile and was well-tolerated by many [patients](#), despite some isolated [adverse events](#).

"We are very encouraged by our trial results showing that CBD was safe and well-tolerated for most patients, and that seizures dropped significantly," says Devinsky. "But before we raise hopes for families who regularly deal with the devastation of treatment-resistant epilepsy, more research, including further studies through our ongoing randomized controlled trial, are needed to definitively recommend CBD as a treatment to patients with uncontrolled seizures."

How the Research Was Conducted

The study was an open-labeled trial, meaning that both the researchers and participants' families knew they were receiving CBD, a compound in medical marijuana that does not contain psychoactive properties.

Between January 15, 2014, and January 15, 2015, 214 patients between 1 and 30 years of age with intractable, or treatment-resistant, epilepsy were enrolled in the trial. Of that cohort, 162 (76 percent) had at least 12 weeks of follow-up after the first dose of CBD and were included in the safety and tolerability analysis. In addition, 137 of the original study cohort (64 percent) were included in the analysis to determine the drug's efficacy.

Patients were given an oral CBD regimen from 2-5 mg/kg per day, with a dose up-titrated until intolerance occurred or to a maximum dose of 25 mg/kg or 50 mg/kg per day, depending on the trial site. Seizures were recorded by parents or caregivers in diaries and reviewed by the study team at each visit.

Lab screenings also were conducted at baseline, and after 4, 8 and 12 weeks of CBD treatment. The study showed variability in responses of individual seizure types to cannabidiol treatment. For example, the median change in total seizures was 34.6 percent, with the greatest reduction occurring in patients with focal and atonic seizures followed by tonic or tonic-clonic seizures. Two patients were free of all seizure types over the entire 12 weeks.

Adverse events were reported among participants, including drowsiness, decreased appetite, diarrhea, fatigue and convulsion. Most were mild to moderate and transient, but 20 patients had serious adverse events related to CBD use -most commonly status epilepticus, or [seizures](#) that last too long or too close together. Five patients had to discontinue treatment due to these adverse events.

Devinsky is currently leading a randomized, controlled trial - considered

the gold standard of scientific research -in which CBD or a placebo is randomly assigned to patients to better tease out the drug's effects and better eliminate research bias.

"I empathize with parents who are looking for answers and will try anything to help their children suffering the devastating effects of intractable epilepsy. But we must let the science, and not anecdotal success stories and high media interest, lead this national discussion," cautions Devinsky. "Taking CBD in a controlled medical setting is vastly different from going to a state where [medical marijuana](#) is legal and experimenting with dosing and CBD strains."

The 11 sites included in the trial are NYU Langone Medical Center; Children's Hospital of Philadelphia; Massachusetts General Hospital for Children; Ann & Robert H Lurie Children's Hospital of Chicago; Benioff Children's Hospital, University of California, San Francisco; Miami Children's Hospital; Pediatric and Adolescent Neurodevelopmental Associates in Atlanta; Texas Children's Hospital; University of Utah Medical Center and Primary Children's Hospital; Wake Forest School of Medicine; and Nationwide Children's Hospital.

Provided by New York University School of Medicine

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