

AAN 69th ANNUAL MEETING ABSTRACT

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Abstract Title: Cannabidiol (CBD) significantly reduces drop seizure frequency in Lennox-Gastaut syndrome (LGS): results of a dose-ranging, multi-center, randomized, double-blind, placebo-controlled trial (GWPCARE3)

Press Release Title: Cannabis-based Medicine May Cut Seizures in Half for Those with Tough-to-treat Epilepsy

Objective: Evaluate efficacy of add-on CBD for the treatment of drop seizures associated with LGS.

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Background: Class 1 evidence of efficacy with CBD in epilepsy is needed. This is the second controlled trial of CBD oral solution in LGS.

Design/Methods: Eligible patients were 2–55 years old with a clinical diagnosis of LGS, ≥ 8 drop seizures during 4-week baseline, and documented failures on ≥ 1 antiepileptic drug (AED). Patients were randomized (1:1:1) to receive CBD 20mg/kg/day, CBD 10mg/kg/day, or placebo for 14 weeks (2-week titration; 12-week dose maintenance). The primary efficacy endpoint was percentage change from baseline in drop seizures/month over the 14-week treatment period for CBD vs placebo.

Results: 225 patients were randomized (76 CBD 20mg/kg, 73 CBD 10mg/kg, 76 placebo); 9 CBD 20mg/kg, 2 CBD 10mg/kg, and 2 placebo patients withdrew early. Groups were similar at baseline; mean age was 16 years (30% of patients ≥ 18 years) and median monthly drop seizure frequency was 85 (IQR: 44, 168). Patients had previously failed a median of 6 and were taking a median of 3 AEDs. Reduction in drop seizure frequency was significantly greater for CBD 20mg/kg (42%) and CBD 10mg/kg (37%) than placebo (17%; $p=0.0047$ and $p=0.0016$). Adverse events (AEs) occurred in 94% of CBD 20mg/kg, 84% of CBD 10mg/kg, and 72% of placebo patients, and most were mild or moderate; the two most common were somnolence and decreased appetite. Treatment-related serious AEs were reported in 5 CBD 20mg/kg, 2 CBD 10mg/kg, and 0 placebo patients. Some elevations in transaminases were seen. There were no deaths. Of the 212 completers, 99% entered the open-label extension study.

Conclusions: Results suggest that CBD add-on therapy for the treatment of drop seizures associated with LGS may be efficacious, with more adverse events than placebo but generally well-tolerated. (NCT02224560)

Study Supported By: GW Research, Ltd