A Study to Evaluate the Efficacy and Safety of Cannabidiol Oral Solution (CBD-OS [GWP42003-P, JZP926]) for the Treatment of Focal-Onset Seizures

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 12 years to 75 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Participants are eligible to be included in the main study only if all of the following criteria apply:

1. Participant has a documented diagnosis of focal epilepsy according to the ILAE Classification of Epilepsy, 2017, characterized by focal seizure types with typical interictal/ictal EEG findings (eg, history of an EEG with focal sharp waves or slowing). Participants with a documented diagnosis of focal epilepsy and a normal EEG are eligible for inclusion.
2. Participant is currently treated with at least 1, but no more than 4, antiseizure medications on a stable regimen.
3. Participant is aged 12 to 75 years old, inclusive, at Screening.

Participants are excluded from the study if any of the following criteria apply:

1. Has a concurrent, confirmed diagnosis of non-epileptic seizures or events that can confound the assessment of the efficacy measures, in the opinion of the investigator.
2. Has clinically significant unstable medical condition(s), other than epilepsy.
3. History of suicidal behavior, current suicidal risk as determined from history, or presence of active suicidal ideation as indicated by a positive response to Item 4 or Item 5 on the C-SSRS or is considered at risk of suicide or self-harm based on the clinical judgement of the investigator following interview with the participant and/or caregiver.
4. Has known or suspected hypersensitivity to cannabinoids or any of the excipients of the study intervention, such as sesame oil.
5. Is currently treated with Epidiolex or received treatment with Epidiolex within 28 days prior to Screening (Visit 1).
6. Is currently using or has used recreational or medicinal cannabis, cannabinoid/CBD based medications, products, or supplements (botanical or synthetic) within 28 days prior to Screening (Visit 1) and/or is unwilling to abstain for the duration of the study.
7. Presence of only nonmotor focal aware seizures or primary generalized epilepsies.

Conditions & Interventions

Interventions:
DRUG: CBD-OS
Conditions:
Focal Seizures
Keywords:
Focal Seizures

More Information

Description:
Cannabidiol oral solution (CBD-OS) is approved in the US for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or Tuberous sclerosis complex (TSC) in patients 1 year of age and older. This study will assess the efficacy and safety of CBD-OS in participants aged 12 to 75 years for the treatment of focal-onset seizures (FOS).

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Phase: PHASE1
IRB Number:
System ID: NCT07233239

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