A Double-blind, Randomized, Placebo-controlled Study to Investigate the Efficacy and Safety of Cannabidiol (GWP42003-P, CBD) as Add-on Therapy in Patients with Tuberous Sclerosis Complex Who Experience Inadequately-controlled Seizures (Study recruitment scheduled to close August 2018) [NCT02544763](https://clinicaltrials.gov/ct2/show/NCT02544763?term=GWP42003&rank=9)

**How long is the study?** Study length: 5 weeks of baseline and 16 weeks of treatment followed by a one- year Open Label Extension (subjects in the United States will have the option to continue for an additional year in the Open Label Extension).

**Who is eligible?** Participants must have a well-documented history of epilepsy as well as a TSC diagnosis confirmed by clinical exam or genetic testing consistent with the criteria set forth in the 2012 International TSC Consensus Conference. All medications or interventions for epilepsy must be stable for one month prior to the trial.

|  |  |  |
| --- | --- | --- |
| Criteria | Column 1 | Column 2 |
| Do you/your child have a definite diagnosis of TSC confirmed by physical exam or DNA testing? | Yes | No |
| Do you/your child have current seizures | Yes | No |
| Are you/your child at least one year old and not older than 65 years old? | Yes | No |
| I/my child is not taking an oral mTOR inhibitor (rapamycin, Rapamune, Afinitor). | Not taking | Taking |
| I/my child has not taken felbamate  OR  I/my child is taking felbamate and has been on it for more than one year. | Not taken  Or  Taking more than 1 year | Taking and on less than 1 yr |
| I/my child has not had surgery in the past 6 months, nor do we have a planned surgery. | No surgery | Surgery |
| I/my child has not had general anesthesia in the past 4 weeks, nor do we have a current procedure scheduled that will require general anesthesia. | No anesthesia | Anesthesia |
| I/my child has not been exposed to cannabis or cannabinoid-based therapies. | No cannabis | Cannabis |
| I/my child will abstain from any cannabis/cannabinoid use for the length of the study, if selected for the study. | Yes | No |

Participants must not be currently using or have in the past 3 months prior to screening used recreational or medicinal cannabis, or cannabinoid-based medications. Participants must be willing to abstain from any cannabis exposure for the duration for the study.

If your response to each question/statement in the above Table is in Column 1, you may be eligible to participate in this clinical trial.

**Note:** Participants will be randomly assigned to either placebo or active treatment groups (added to their existing medications). All patients who complete the trial will be invited to participate in the open label extension, where all receive active treatment. Travel assistance may be provided on a case by case basis, if required.

Please review the full summary of criteria at the [link](https://clinicaltrials.gov/ct2/show/NCT02544763?term=GWP42003&rank=9) provided. If you believe you are eligible to participate, contact [JNakagawa@tsalliance.org](mailto:JNakagawa@tsalliance.org) or [medinfo.usa@gwpharm.com](mailto:medinfo.usa@gwpharm.com).