The effects of cannabidiol (CBD) on electrical and autonomic cardiac function in children with severe epilepsy

NCT02815540

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PARENT/GUARDIAN CONSENT FORM

The effects of cannabidiol (CBD) on electrical and autonomic cardiac function in children with severe epilepsy

You and your child are invited to participate in a research study on the effects of medical marijuana in the form of cannabadiol (CBD) oil on cardiac function, dysautonomia symptoms, and seizure frequency in children and young adults with Dravet syndrome or Lennox-Gastaut syndrome. Your child was selected as a possible participant because your child was registered or is planning to register with the state dispensary to receive medical marijuana in the form of cannabadiol oil, and also because your child is diagnosed with Dravet syndrome or Lennox-Gaustaut syndrome. Receiving CBD is not part of this study. This study is being done to collect cardiac and dysautonomia information from patients who are already taking CBD. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Beverly S. Wical, M.D., Kari Williams, M.P.H., and Samuel Roiko, Ph.D. The cardiac equipment used for this study is funded by private donors through the Gillette Children's Specialty Healthcare Foundation.

Study Purpose

This study is for children and young adults aged 2 years to 30 years diagnosed with Dravet syndrome or Lennox-Gastaut syndrome. Length of participation will be approximately 2 months.

The purpose of the study is to determine what effect cannabadiol has on your child's cardiac function, dysautonomia symptoms, and seizure frequency. Signs and symptoms of dysautonomia include change of skin color in hands and feet, sweating, increase in pupil size, flushing, feeding issues, increased heart rate, strong emotions, constipation, increase in urination or bowel movement issues, and irritability.

Study Procedures

This study is for children and young adults either already on medical marijuana in the form of cannabadiol oil, or for those who are planning to go on to the medical cannabadiol oil.

If your child is not yet on the cannabadiol, we will ask you to complete a 7-day seizure diary, complete a questionnaire on dysautonomia symptoms, do a 12-Lead ECG (Electrocardiogram) to record your child's heart function, and to wear a Holter monitor to record your child's heart function for 24 hours. If your child can lie still for about 20 minutes, we will do a signal average ECG on the same day as the 12-Lead ECG. This special ECG will run for 20 minutes, and will take an average of your child’s readings. You and your child can opt out of doing the signal average ECG. We will ask you and your child to do these procedures prior to taking any cannabadiol from the state dispensary. These procedures will be recorded as your child's baseline readings. The 12-Lead ECG, the signal average ECG, and the Holter monitor are non-invasive devices to record electrical activity of your child's heart. Once your child has been on the medical cannabadiol for at least 4 to 8 weeks, we will ask you to do the 7-day seizure diary, the dysautonomia questionnaire, the 12-

Lead ECG, the signal average ECG, and the 24-hour Holter monitoring again to determine whether anything has changed in your child's seizure frequency, heart function, or dysautonomia symptoms.

If your child is already on medical cannabadiol, but is planning to quit taking the drug, we will ask you to do the 7-day seizure diary, the dysautonomia questionnaire, the 12-Lead ECG, the signal average ECG, and the 24-Hour Holter monitoring before your child quits taking the cannabadiol. Then 4 to 8 weeks after your child has stopped taking the cannabadiol, we will ask you to do all of these tests again to record the changes in seizure frequency, dysautonomia symptoms, and heart function.

During the study, study personnel will also collect information on any side effects your child may have and any treatments received to combat side effects.

During the study, we will also request access to your child's medical records for diagnostic and treatment information for study purposes.

Risks of Study Participation

There is a small risk for loss of privacy when study personnel look at your child's medical records. This is minimized by assigning your child a study ID number, instead of using their identifying information during the study.

ECG risks: There is no pain during an ECG; however, the ECG patches may be cold and removing the pads may make the skin red and sore. In some cases, the locations where the ECG patches are placed may need to be shaved.

24-hour Holter monitor risks: There is no pain during the use of a 24-hour Holter monitor; however, the patches may be cold and removing the pads may make the skin red and sore. In some cases, the locations where the patches are placed may need to be shaved.

Benefits of Study Participation

There are no direct benefits for your child while participating in this study. However, the knowledge we gain may help to improve treatment for Dravet syndrome and Lennox-Gastaut syndrome in the future.

Alternatives to Study Participation

The alternative to study participation is to not join the study.

Study Costs/Compensation

There are no costs to you or your child for participation in this study, except for your contributed time and travel costs. There is no compensation for participating in this study.

Research Related Injury

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your child's insurance company. If you think that your child has suffered a research related injury, let the study physicians know right away.

Confidentiality

The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify your child as a participant. Your child's record for the study may, however, be reviewed by the study doctor and his study personnel and by departments at the University with appropriate regulatory oversight. Your child will be assigned a study ID number to protect his/her identity. Your consent to this study will be recorded in your child's medical record and in your child's research folder, and the heart tests will be recorded in your child's medical record and in your child's research folder. All paper copies of your questionnaire's and diaries will be marked with your child's study ID number and stored in your child's research folder. To these extents, confidentiality is not absolute. Study data will be encrypted according to current University policy for protection of confidentiality. All paper copies of data will be kept in a locked drawer in the investigator's office or in the study coordinator's office.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

Protected Health Information (PHI)

Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with Gillette Children's Specialty Healthcare. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Contacts and Questions

The researchers conducting this study are Beverly S. Wical, M.D, Kari Williams, M.P.H., and Samuel Roiko, Ph.D. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact them at:

Beverly S. Wical, M.D. 651-229-3870

Kari Williams, M.P.H.	**651-325-2316**
Samuel Roiko, Ph.D.	**651-578-5233**

You may also contact the **research coordinator at 651-325-2314.**

Out of Study Contact

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), contact *Patient Representative of the Quality Improvement Resources Department* at Gillette Children's Specialty Healthcare, 200 East University Avenue, St. Paul MN 55101, Telephone 651-229-1706 or 1-800-719-4040 (toll free) or e-mail qualityrep@gillettechildrens.com.

To share feedback privately about your research experience, including any concerns about the study, call the Research Participants Advocate Line: 612-625-1650 or give feedback online at www.irb.umn.edu/report.html. You may also contact the Human Research Protection Program in writing at D528 Mayo, 420 Delaware St. Southeast, Minneapolis, Minnesota 55455.

You may also send feedback by going to: https://www.gillettechildrens.org/contact-us/ and completing the feedback form.

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to have my child participate in this study.

Printed Name of Participant _____

Signature of Parent_____

Date_____

Signature of Legal Representative _____

Date _____

Signature of Person Obtaining Consent_____

Date_____