Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Efficacy of Cannabidiol (CBD) in Patients with Treatment-Resistant Frontal Lobe Epilepsy

Protocol summary

Study aim

Evaluation of the effectiveness of cannabidiol on the seizure frequency, seizure severity, and quality of life in patients with drug-resistant frontal lobe epilepsy

Design

Placebo-controlled, randomized, concealed, blinded, phase 3 clinical trial with a parallel group design of 15 patients in each group. A random number table has been used for randomization.

Settings and conduct

Patients with drug-resistant frontal lobe epilepsy were selected from previously evaluated patients at the epilepsy monitoring clinic of Imam Khomeini Hospital in Tehran and will be recruited to the study within four weeks. Measures such as clinical evaluations (number of seizures and severity of seizures) and quality of life questionnaire are performed and recorded before and after the intervention. A drug or placebo is given for 14 weeks. The administered dose will be 70 mg, 140 mg, and 210 mg in the first, second, and third to fourteenth weeks respectively. A telephone follow-up of patients will be considered once every two weeks.

Participants/Inclusion and exclusion criteria

Inclusion criterion is the diagnosis of focal refractory frontal lobe epilepsy (no response or inadequate response to treatment with two or more common antiepileptic drugs) and exclusion criteria are History of marijuana or cannabis use in recent month, pregnancy, and use of any of the drugs Clobazam, Des-methyl clobazam, Eslicarbazepine, Topiramate, Zonisamide, and Warfarin.

Intervention groups

Patients are divided into two groups: intervention and placebo. Each of these groups received a specific dose as a solution containing 40 mg of drug or placebo per ml prepared by KMT company containing cannabidiol and placebo, respectively.

Main outcome variables

Decrease the seizure frequency following cannabidiol use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210608051515N1**
Registration date: **2021-06-12, 1400/03/22**
Registration timing: **prospective**

Last update: **2021-06-12, 1400/03/22**
Update count: **0**

Registration date

2021-06-12, 1400/03/22

Registrant information

Name

Seyyed Reza Ebadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-21, 1400/04/30

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Cannabidiol (CBD) in Patients with Treatment-Resistant Frontal Lobe Epilepsy

Public title

Canabidiol (CBD) for Treatment of Frontal Lobe Epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Drug resistant frontal lobe epilepsy diagnosis (Insufficient or no response to two or more of anti epileptic agents)

Exclusion criteria:

Consumption of any derivative of marijuana or cannabis plant in recent month Pregnancy Any of the aforementioned medications in regimen: Clobazam, DesMethyl Clobazam, Eslicarbazepin, Topiramate, Zonisamide, Warfarin

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization coincides with the allocation concealment by generating random codes - consisting of an English letter and two digits - generated using one of the web resources (here is random.org), printing the codes on a card, and placing the cards in a sealed envelope (SNOSE method). After generating the code list, fifteen codes will be assigned to the drug group, and the other fifteen codes are assigned to the placebo group (alternately assigned). This list will be delivered to the drug supplier, and each code is displayed properly as a label on the body of the drug box or placebo. Each code will be printed on one card that, after shuffling, are placed in opaque envelopes with aluminum inner lining numbered from 1 to 30, and the envelope lid will be completely sealed. The envelopes will be placed in a box and handed over to another researcher responsible for delivering the drugs to the participants. The patients who will be referred to assign to one of the two groups will be given an envelope. The envelope will be taken out of the box orderly, and the seal will be broken. According to the code in the envelope, the right drug box or placebo is delivered to the patient, and the patient's credentials are written on the envelope. Also, in a separate list, the person is assigned to the code taken out of the envelope. Thus, subsequent visits for re-delivery of the box containing a drug or placebo will be done precisely based on their code. In contrast, the researcher responsible for allocating patients and the participant themselves will not be aware of the type of intervention they will offer and receive. (Generating of the codes and assigning half of the codes to the intervention and the other half to the control will be done by another researcher who will not be responsible for these steps or any other steps)

Blinding (investigator's opinion)

Triple blinded

Blinding description

Study participants will all be unaware of their group (drug or placebo) even though they know they will participate in a study that they will be given one of the two options: drug or placebo. Also, patients and personnel are completely blinded due to the exact similar label and specifications on boxes, color, taste, smell, and consistency between the drug and placebo. Clinical caregivers, researchers, and physicians responsible for diagnosis and treatment will be unaware of the type of treatment assigned to each participant. Those responsible for evaluating the results will also evaluate data and perform the statistical analysis by coding individuals without being aware of the patient group - drug or placebo. The Data Safety and Monitoring Committee is also unaware of people who have received the drug or placebo and only monitors the above-mentioned principles according to blinding، concealment, and data collection protocols.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine-Tehran University of Medical Sciences, Biomedical Research Ethics Committee

Street address

Room 605، Secretariat of the Ethics Committee in University Biomedical Research، Vice Chancellor for Research and Technology, 6th Floor, Central University Organization, Corner of Ghods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-05-01, 1400/02/11

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.130

Health conditions studied

1

Description of health condition studied
Treatment Resistant Epilepsy
ICD-10 code
G40
ICD-10 code description
Epilepsy and recurrent seizures

Primary outcomes

1

Description
Decrease in the seizure frequency in drug-resistant frontal lobe epilepsy following cannabidiol use
Timepoint
Before the intervention and after 14 weeks of taking the drug or placebo
Method of measurement
Based on the patient's history and counting the number of seizures per month

Secondary outcomes

1

Description
Decrease in the severity of seizures after taking cannabidiol according to the Chalfont seizure severity scale
Timepoint
Before the intervention and after fourteen weeks of taking drug or placebo
Method of measurement
Based on the Chalfont seizure severity by scoring system

2

Description
Increase in quality of life in epilepsy following cannabidiol use
Timepoint
Before the intervention and after the fourteen weeks of taking medication or placebo
Method of measurement
Quality of Life in Epilepsy with 31 questions (QOLIE-31) questionnaire by scoring

Intervention groups

1

Description
Intervention group: Patients diagnosed with frontal lobe epilepsy who are resistant to common drug therapies. These patients are randomly assigned to the intervention group according to the conditions previously described. Cannabidiol in liquid form containing 40 mg per ml of the active substance (Cannabidiol or CBD) with an appropriate amount of preservatives and flavorings according to the protocol prepared by Khosro Medisa-Teb (KMT) pharmaceutical company. It will be prescribed 70 mg (equivalent to 1.75 ml) in the first week, then 140 mg (equivalent to 3.5 ml) in the second week, and 210 mg (equivalent to 5.25 ml) in the third to fourteenth weeks as a single dose (Daily - qDay). From the beginning of the intervention, the patient continues to take the drug for fourteen weeks, and the necessary evaluations will be performed at intervals according to the predefined schedule. The way to take the drug, which is in liquid form and should be taken using a graduated dropper embedded in the medicine package, will be fully explained by the person delivering the medicine.
Category
Treatment - Drugs

2

Description
Control group: Patients diagnosed with frontal lobe epilepsy who are resistant to common drug therapies. These patients are randomly assigned to the control group according to the previously described conditions. Placebo will be prepared according to the specific protocol of Khosro Medisa-Tab (KMT) Pharmaceutical Company, which is in the form of liquid without active ingredient (Cannabidiol or CBD) and contains an appropriate amount of preservatives and flavorings. It is the same in terms of color, smell, consistency, and taste as the drug. This product will be prescribed in the first week equal to 1.75 ml and then in the second week equal to 3.5 ml and the third week until the fourteenth week equal to 5.25 ml as a single dose (daily - qDay). From the beginning of the placebo administration, the patient continues to take the placebo for fourteen weeks, and the necessary evaluations are performed at intervals according to the specified schedule. The way to take medicine, which is in liquid form and should be taken using a graduated dropper embedded in the medicine package, will be fully explained by the person delivering the medicine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran, Imam Khomeini Hospital Complex
Full name of responsible person
Abbas Tafakhori
Street address
Epilepsy Clinic, First Floor, Center of Neurological Diseases Research Building, Imam Khomeini Hospital Complex, Baqer Khaan Ave., Chamraan Highway, Tehran, Tehran

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Street address
Sixth Floor, Deputy Department of Research and Technology, Central Building of the University of Medical Sciences, Quds Ave., Keshavar Blvd.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
KMT Pharmaceutical Company
Proportion provided by this source
80
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Seyyed Reza Ebadi
Position
Physician Researcher
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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seyyedrezae@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The data of the study participants will be evaluated for statistical analysis, and their results will be published in the form of an article.
When the data will become available and for how long
Immediately after the publication of the results in the form of a scientific article, the results of data analysis will be available to researchers at the request of the data.
To whom data/document is available
Researchers of this project and individuals who have the right to access the project data based on the written permission of the corresponding researcher can access the project data.
Under which criteria data/document could be used
If the permission of the main researcher of the project is obtained with an acceptable justification and explanation, the data obtained from this project can be used.
From where data/document is obtainable
Imam Khomeini Hospital Complex, Neurological Diseases Research Center, Second Floor, Epilepsy Monitoring Unit, Research Unit
What processes are involved for a request to access data/document
A written request will be sent to the researcher in charge of the study (Dr. Abbas Tafakhori) with appropriate evidence and justification; Once approved by him, access to data and documents will be possible.
Comments