Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of cannabidiol in the treatment of adult dystonias-a randomized placebo-controlled clinical trial

Protocol summary

Study aim
Evaluation of the effectiveness of liposomal cannabidiol on the improvement of motor symptoms in patients with generalized and focal dystonia compared with placebo

Design
Randomised, superiority, parallel group trial with blinded outcome assessment. stratified randomized ,phase 3 on 60 patients

Settings and conduct
At the Neurology Clinic, after selecting patients, the intervention is performed for 9 weeks. Before receiving the intervention and then at the end of the third, sixth and ninth week of the intervention, the severity of motor symptoms,It is measured by a researcher who is blind to the type of intervention, based on the corresponding movement scales in two groups. The intervention is then discontinued for 5 weeks.At the beginning of the second period, the crossover is performed and the control and intervention groups are changed.The measurements will be performed in the same way as the first period.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of generalized or focal dystonia based on clinical signs Age over 18 years Lack of complete control of dystonia symptoms with drug therapy Exclusion criteria: There is any evidence that dystonia is secondary Recent stroke or heart attack High blood pressure Cognitive impairment Recorded history of psychiatric disorders History or current substance abuse Current use of anticoagulants History of liver disease Pregnancy or intent to conceive or breastfeed History of dystonic surgery Sensitivity to soy

Intervention groups
Intervention:Liposomal cannabidiol oil at a dose of 10 mg every 6 hours for 9 weeks, starting at a dose of 10 mg every 12 hours and increasing to the target dose within 5 days Placebo:similar to the intervention group

Main outcome variables
Severity of dystonic motor symptoms, Van Marsden Scale and Global Dystonia Scale,TWSTRS scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211019052811N1**
Registration date: **2021-11-27, 1400/09/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-27, 1400/09/06**
Update count: **0**

Registration date
2021-11-27, 1400/09/06

Registrant information

Name
zeinab ameli

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
2021-11-22, 1400/09/01

Expected recruitment end date
2022-09-23, 1401/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effect of cannabidiol in the treatment of adult dystonias-a randomized placebo-controlled clinical trial

Public title
Evaluation of the effect of cannabidiol in the treatment of dystonia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with focal-generalized dystonia Failure to improve the patient's dystonic symptoms with previous drug treatments
Exclusion criteria:
Evidence that dystonia is secondary to other diseases History of liver disease Pregnancy or intent to conceive or breastfeed History of dystonic surgery, including deep brain stimulation and destructive surgery
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of patients in two groups is done using stratified randomization method. Due to the existence of two types of dystonia, we perform the block randomization method within each class. For this purpose, within each class, blocks with size a, b) aabb, abab, abba, baba, bbaa, baab) are randomly selected and patients Will be assigned to treatments according to this random sequence.To match the manual intensity in the treatment groups, for each intensity, a random sequence is created by blocking method with size 2 or 4, and the patients are assigned to the treatment group based on the obtained sequence.We use the tool for block randomization using the sealed envelope site
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients receiving cannabidiol and placebo are blind to receiving the drug and the severity of motor symptoms is assessed by the researcher in relation to the type of blind intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Ahmad Abad Ave,Hospital Ghaem
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Approval date
2021-10-19, 1400/07/27
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.461

Health conditions studied

1

Description of health condition studied
dystonia
ICD-10 code
G24
ICD-10 code description
Dystonia

Primary outcomes

1

Description
Intensity of dystonia motion symptoms based on Van Marsden Scale and Global Dystonia Scale and TWSTRS
Timepoint
Before the intervention (0), then 3, 6, and 9 weeks after the start of the intervention or placebo
Method of measurement
Van Marsden Scale and Global Dystonia Scale and TWSTRS

Secondary outcomes

1

Description
Quality of life using SF-36 questionnaire
Timepoint
Before the intervention (0), then 3, 6, and 9 weeks after the start of the intervention or placebo
Method of measurement
SF-36 questionnaire

Intervention groups

1

Description

Intervention group:Liposomal cannabidiol drops are given at a dose of 10 mg every 6 hours. The drug is started with a dose of 10 mg every 12 hours (2 ml) and after 5 days is increased to a dose of 10 mg every 6 hours. Due to the divided dose of the drug, the patient will be more tolerant of the dose of the drug.The patient's previous treatments are reviewed and kept constant from one month before the end of the study.Patients receive the intervention for 9 weeks. Once before receiving the intervention and then at the end of the third, sixth and ninth week of the intervention, the severity of motor symptoms is measured by the researcher, who is blind to the type of intervention, based on the relevant movement scales in both groups.After the first period, it will be August 5 for 5 weeks and the intervention will be stopped in both groups. At the beginning of the second period, crossover is performed and patients who received the main drug in the first period will be assigned to the placebo group and those who received the placebo first will be assigned to the main drug group. The measurements will be performed in the same way as the first period.

Category

Treatment - Drugs

2

Description

Control group:Pharmacopoeia receive exactly the same drug as the main drug in the form of drops with the same color and taste as the main drug.Then, as in the intervention group, other actions are performed

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem Hospital Clinic

Full name of responsible person
Zeinab Ameli

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Ahmad Abad Ave,Ghaem Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Olfati Nahid

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Neurology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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