Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Effects of oral cannabidiol (CBD) usage on variable severity of spasticity in multiple sclerosis patients with gait problem caused by their spasticity. A Double-Blind Randomised Controlled Trial

Protocol summary

Study aim

Determining the effects of oral Cannabidiol administration on the severity of spasticity in multiple sclerosis (MS) patients with gait disorder due to spasticity

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 30 patients in each group. A table of random numbers has been used for randomization.

Settings and conduct

This study will be conducted in several centers in the cities of Mashhad, Tehran and Sari. The main center will be the neurology clinic of Qhaem Hospital of Mashhad University of Medical Sciences, and the patients will be given Cannabidiol oral drops and placebo. Cannabidiol starts at 2.5 mg (twice a day) and up to 35 mg in the first week, and if there is no adequate response, it will be increased to the tolerance level, and they will be followed up to 8 weeks after the start of consumption. Questionnaires of fatigue, quality of walking, urinary frequency, sleep, and pain will be measured before starting the drug and after 4 and 8 weeks from the start. Also, the patient's quality of life will be measured using EuroQoL before and after 8 weeks of the intervention. In addition, telephone follow-up of patients once every two weeks will be considered.

Participants/Inclusion and exclusion criteria

The condition of entering the patient is a definite diagnosis of MS based on McDonald's criteria and gait disorder, the conditions of non-entry include pregnancy, a history of using cannabis derivatives, taking drugs with liver metabolism, or suffering from liver dysfunction.

Intervention groups

Patients are divided into two intervention and placebo groups, each of these groups receives a specific dose (40 mg/ml) of the oral solution of the drug or placebo from Khosro Medisa Teb Company.

Main outcome variables

The intensity of the patient's spasticity based on the Numeric rating scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220815055709N1**
Registration date: **2022-12-17, 1401/09/26**
Registration timing: **prospective**

Last update: **2022-12-17, 1401/09/26**
Update count: **0**

Registration date

2022-12-17, 1401/09/26

Registrant information

Name

Mohammad Ali Nahayati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2000

Email address

nahayatia@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-01-30, 1401/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of oral cannabidiol (CBD) usage on variable severity of spasticity in multiple sclerosis patients with gait problem caused by their spasticity. A Double-Blind Randomised Controlled Trial

Public title

The effect of using Cannabidiol on the severity of spasticity in MS patients with gait disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of MS based on McDonald's 2017 criteria by a neurologist Expanded Disability Status Scale lower than (EDSS<7) Patients with gait disorder Age above 18 years

Exclusion criteria:

History of any liver dysfunction Known sensitivity to any component of the drug Taking drugs with liver metabolism such as Warfarin, Clobazam, and Sodium valproate Pregnancy or breastfeeding Use of marijuana or cannabis-derived compounds in the last 6 months

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the arrival time of the patients, the patient himself draws a number from 1 to 60. These numbers are defined by the main analyzer in the pre-prepared tables as placebo or the main drug. In addition, the arrangement of numbers and drugs has been randomized once by the main analyzer as a lottery. We have 60 patients divided into two groups (i.e. original drug and placebo). Therefore, out of 60 numbers, 30 numbers belong to patients (cases) and 30 numbers belong to controls. We write the name of the case or control on the paper and put them in an open box and randomly 60 patients choose them and do not see the result and give us the paper.

Blinding (investigator's opinion)

Double blinded

Blinding description

Study participants will all be unaware of the group, despite being assured that they will be taking part in a study that will take either drug or placebo. Also, due to the completely similar label and specifications on the medicine bottle and placebo, the color, taste and consistency of the contents of the box are also completely blinded. Medicines are given in unmarked packages and shown to the clinical caregiver who is not in the process of treating the patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculty of Medicine, Mashhad University of Medical Sciences

Street address

Mashhad Faculty of Medicine, Eastern Door of University Campus, Azadi Square, Mashhad, Khorasan Razavi

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2022-06-14, 1401/03/24

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.194

Health conditions studied

1

Description of health condition studied

Spasticity in multiple sclerosis patients with gait problem

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

The severity of spasticity in Multiple sclerosis patients with gait problem following the use of Cannabidiol

Timepoint

The severity of the patient's spasticity before starting the drug and after 3 and 6 weeks from the start

Method of measurement

Severity of spasticity will be measured based on Numeric

rating scale (0-10)

Secondary outcomes

1

Description
Quality of patient's life
Timepoint
The patient's quality of life will be measured before and after 8 weeks of the intervention.
Method of measurement
Patient quality of life will be measured using The European Quality of Life scale.

2

Description
The severity of the patient's gait problem
Timepoint
The severity of the patient's gait disorder will be measured at the beginning and after 6 weeks from the start of the study.
Method of measurement
The severity of the patient's gait problem using a SF12 short questionnaire with 12 questions.

3

Description
Sleep quality
Timepoint
Sleep quality will also be measured at the beginning and after 6 weeks from the beginning of the study.
Method of measurement
Sleep quality will be measured using a SF12 short questionnaire with 12 questions.

4

Description
The severity of pain
Timepoint
The severity of pain of the patients will also be measured at the beginning and after 6 weeks from the start of the study.
Method of measurement
Pain of the patients using a SF12 short questionnaire with 12 questions.

5

Description
Patients' Urinary disorders
Timepoint
Urinary disorders of the patients will be measured at the beginning and after 6 weeks from the start of the study.
Method of measurement
urinary disorders of the patients will be measured using a SF12 short questionnaire with 12 questions

Intervention groups

1

Description
Intervention group: MS patients are diagnosed with spasticity and the resulting gait disorder. These patients are randomly assigned to the intervention group according to the described conditions. The drug cannabidiol, which contains 40 milligrams per milliliter of CBD, was prepared by Khosro Medisa teb pharmaceutical company (KMT). In the first week, drug administration will start from 2.5 mg (twice a day) and up to 35 mg in the first week, and if there is no adequate response, it will be increased to the tolerance level and will be followed up to 8 weeks after the first intake. The medication should be taken using the graduated dropper included in the medication package, which will be fully explained by the person delivering the medicine.
Category
Treatment - Drugs

2

Description
Control group: patients diagnosed with MS with spasticity and the resulting gait disorder. These patients are randomly assigned to the control group according to the described conditions. The placebo prepared based on the special protocol of Khosro Medisa teb Pharmaceutical Company (KMT) is prepared as a liquid without medicinal substance (Cannabidiol-CBD). The drug consumption in the first week starts from 2.5 mg (twice a day) and goes up to 35 mg in the first week and is used up to 8 weeks after the first use. How to take the medicine, which is in liquid form, should be fully explained by the person providing the medicine, using the graduated dropper built into the closed medicine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
MS Clinic of Ghaem Mashhad Hospital
Full name of responsible person
Mohammad Ali Nahayati
Street address
Ghaem Hospital, Ahmadabad Street, Mashhad, Khorasan Razavi
City
Khorasan Razavi
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 51 3840 0001
Email

b.ghaem@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khosro Medisa Teb Company
Full name of responsible person
Masoud Saghafi
Street address
Number 21, Jooybar Alley, Shad St, Molla Sadra St, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435791999
Phone
+98 21 8862 2761
Email
contact@kmtmed.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khosro Medisa Teb Company
Proportion provided by this source
100
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
Ghaem Hospital Mashhad
Full name of responsible person
Pegah Mousavi
Position
Residency
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
Street address
Ghaem Hospital, Ahmadabad Street, Mashhad, Khorasan Razavi
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 21 3840 0001
Email
Pegahmsv@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ghaem Hospital Mashhad
Full name of responsible person
Mohammad Ali Nahayati
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Neurology
Street address
Ghaem Hospital, Ahmadabad Street, Mashhad, Khorasan Razavi
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 21 3840 0001
Email
NahayatiA@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Khosro Medisa Teb Company
Full name of responsible person
Melika Ansari
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Medical Nanotechnology
Street address
Number 21, Jooybar Alley, Shad St, Molla Sadra St, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435791999
Phone
+98 21 8862 2761
Email
contact@kmtmed.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
MS Clinic, Ghaem Hospital Mashhad
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 with appropriate evidence and justification; Once approved by him, access to data and documents will be possible.
Comments