

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)

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+98 51 3800 2000

Email address

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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

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9176699199

Phone

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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,
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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

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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

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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

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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