

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of Cannabidiol drop with Pramipexole in Restless Leg Syndrome severity index - randomized parallel clinical trial

Protocol summary

Study aim

Comparisons of the improvement of RLS severity between Cannabidiol and Pramipexole

Design

Two arms parallel-group randomized trials with the control group and the intervention group

Settings and conduct

Study groups will be selected from Firoozgar hospital clinic during 2021-2022. For patients in the study, the follow-up questionnaires will be completed over phone calls.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals aged 18-65 years with RLS (according to the International Restless Legs Syndrome Study Group (IRLSSG) diagnostic criteria) with normal CBC, liver function test, BUN, Cr tests during the past year before the study, with serum ferritin level being higher than 50 ng/ml. Exclusion criteria: Taking medications with hepatic metabolisms such as warfarin, anticonvulsants, antibiotics, and dopamine antagonist during the last month before the study, or any drug abuse, anxiety, depression, and impulse control disorders. History of sleep disorders and CNS or PNS disorders or pregnancy, lactation, and soy allergy.

Intervention groups

Intervention group: Cannabidiol drop will be started at the dose of 5mg/day and then titrated up to 5 mg/week for four weeks. Treatment response will be assessed based on the IRLS questionnaire every month for two months after beginning the studied treatment plan. If the patient has an appropriate therapeutic response, titration will stop. Control group: Pramipexole 0.09 mg at midnight started and increased by 0.09 mg weekly to reach 0.36 mg per day. Treatment response is assessed based on the IRLS questionnaire every month for two months after beginning the studied treatment plan.

Main outcome variables

RLS symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210901052359N1**

Registration date: **2021-10-03, 1400/07/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-03, 1400/07/11**

Update count: **0**

Registration date

2021-10-03, 1400/07/11

Registrant information

Name

Tara Khoeini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2237 5287

Email address

tara.khoeini@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Cannabidiol drop with Pramipexole in Restless Leg Syndrome severity index - randomized parallel clinical trial

Public title

Cannabidiol in Restless Leg Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Fulfill RLS criteria based on International Restless Legs Syndrome Study Group (IRLSSG) consensus criteria 2014 Normal CBC, serum AST, ALT, Alp, BUN, Cr Serum ferritin level above 50 ng/ml Informed consent

Exclusion criteria:

Taking drugs that have a hepatic metabolism such as warfarin, anticonvulsants, antibiotics Taking dopamine antagonist drugs and other RLS treatment drugs during the past month History of drug abuses and impulse control disorders History of other sleep disorders History of other diseases related to the peripheral and central nervous systems History of cardiovascular, liver, kidney diseases and arrhythmia Pregnancy, lactation and patients using unsafe contraceptive methods Soy allergy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

For the sampling plan, we will use the randomized quadruple block method to select ten random blocks according to the sample size. Patients will be respectively divided into two groups of A or B based on the randomized orders. Drugs of each group will be given to patients. Due to the different forms of drugs used (syrup and capsule), blinding can not be done; therefore, no concealment will be performed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Tehran Hemat Highway next to Milad Tower. 14535

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-08-30, 1400/06/08

Ethics committee reference number

IR.IUMS.FMD.REC.1400.346

Health conditions studied

1

Description of health condition studied

Restless Leg syndrome

ICD-10 code

G25.81

ICD-10 code description

Restless legs syndrome

Primary outcomes

1

Description

Restless Legs Syndrome Rating Scale

Timepoint

before intervention, 4 and 8 weeks after intervention

Method of measurement

Restless Legs Syndrome Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: KMT(Khosro Medisa Teb) Group Cannabidiol C2 drops containing 5 mg per ml of the liposomal form of cannabidiol will be used. At the beginning of the intervention, one ml will be prescribed every night, and the titration will be done by increasing one cc per week for four weeks and then following up for another four weeks. During the titration phase, we will not increase the dose if the patient's symptoms resolved.

Category

Treatment - Drugs

2

Description

Control group: Pramipexole 0.18 tablets (containing 0.18 mg per tablet) will be used. In the first week, half a pill will be prescribed at night and the titration will be done by increasing half a pill per week for four weeks, and then following up for another four weeks. During the titration phase, we will not increase the dose if the patient's symptoms resolved.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Tara Khoeini

Street address

Firoozgar Hospital, Beh Afarin St., Karim Khan St., Valiasr Sq., Tehran

City

Tehran

Province

Tehran

Postal code

0193747811

Phone

+98 21 8214 1000

Email

h_firoozgar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motevalian

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences, fifth floor of the headquarters

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

research-m@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Tara Khoeini

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

Street address

No. 31, 4th East Aseman St., Saadat Abad, Tehran

City

Tehran

Province

Tehran

Postal code

1998148514

Phone

+98 21 2207 3647

Email

tara.khoeini@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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1998148514

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

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

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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