Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 questionaries 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 sypmtoms

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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Abbas Motevalian

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

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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

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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