# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

04 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

**Street address**
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

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

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+98 21 8670 2503

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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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## Person responsible for scientific inquiries

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**Latest degree**
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**Other areas of specialty/work**
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## Person responsible for updating data

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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