Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

evaluation of the effect of acupuncture in control of the symptoms in patients with restless leg syndrome

Protocol summary

Summary

This study is a randomized, single-blind, non-placebo controlled and single-center clinical trial. The aim of this study is to compare the efficacy of Acupuncture and gabapentin versus gabapentin as a standard treatment for treating the Restless Legs Syndrome. This study includes 46 patients who have Restless Legs Syndrome for over 6 months and have the four diagnostic criteria for Restless Legs Syndrome. Patients with Pregnancy, immune deficiency, cancer, diffuse skin lesions, pacemaker, coagulation disease, infection on the area of acupuncture are not enrolled. Also patients who have systemic disorder such as iron deficiency anemia, thyroid dysfunction, renal failure will be excluded. Using block randomization, patients are categorized to one of two groups: 1. Acupuncture and gabapentin as an intervention group, 2. gabapentin as a control group. All patients after giving ethical consent undergo treatment with 300mg gabapentin tablet daily. Patients in intervention group undergo electro acupuncture for 10 sessions. If after 4 weeks the signs of the patients improved less than 30% according to VAS increase the dosage of gabapentin. Both groups of patients are evaluated by resident of Physical medicine and rehabilitation who are not aware of the type of treatment. This evaluation is performed before, a month later and 2 month after treatment (by visit) via IRLSSG و Pittsburg questioners and Visual analog scales. Finally, statistical comparison of results will perform.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102724742N1**
Registration date: **2015-11-19, 1394/08/28**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-11-19, 1394/08/28

Registrant information

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Samaneh Ghahramanpoori
Name of organization / entity
Iran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source
Iran University of Medical Sciences

Expected recruitment start date

2015-11-06, 1394/08/15

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation of the effect of acupuncture in control of the symptoms in patients with restless leg syndrome

Public title

evaluation of the effect of acupuncture in control of the symptoms in patients with restless leg syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: men and women 18 years old up to 65 years old who have restless legs with duration more than 6 month and have the four diagnostic criteria for Restless Legs Syndrome: 1- an urge to move the legs, 2- that is present at rest, 3- relieved by movement, 4- demonstrates a circadian pattern with peak symptoms occurring at night or in the evening. exclusion criteria: patients who have treatable systemic disorder such as renal failure; iron deficiency anemia; thyroid dysfunction; Patients with Pregnancy; immune deficiency; coagulation disease; cancer; diffuse skin lesions; cardiac pacemaker; infection on the areas of acupuncture also other neurologic disorder such as levodopa dependent dyskinesia; neuroleptic dependent akathisia; Tourette syndrome; attention deficit hyperactivity disorder(ADHD) and anxiety disorders.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Tehran university of medical sciences

Street address

6th floor, Central Organization of university, Keshavarz Boulevard, Tehran

City

Tehran

Postal code

Approval date

2014-07-06, 1393/04/15

Ethics committee reference number

105/1680/93/د

Health conditions studied

1

Description of health condition studied

restless leg syndrome

ICD-10 code

G25.8

ICD-10 code description

Other specified extrapyramidal and movement disorder: Restless legs syndrome Stiff-man syndromes

Primary outcomes

1

Description

severity of leg restlessness

Timepoint

in start of study, first month and second month after start of study.

Method of measurement

International Restless Legs Syndrome Study Group(IRLSSG) questionnaire

2

Description

severity of leg restlessness

Timepoint

in start of study, first month and second month after start of study.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: underwent treatment of 300 mg gabapentin daily concomitant of 10 session 40 HZ frequency electro Acupuncture over 30 minutes over maximum 3 session in weeks during 4 weeks. If after 4 weeks the signs of the patients improved less than 30% according to VAS increase the dosage of gabapentin.

Category

Treatment - Other

2

Description

Control group: underwent treatment of 300 mg gabapentin daily. If after 4 weeks the signs of the patients improved less than 30% according to VAS increase the dosage of gabapentin.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of physical medicine and rehabilitation, Firoozgar Hospital

Full name of responsible person
Samaneh Ghahramanpoori, Resident of physical medicine and rehabilitationi

Street address
Firoozgar Hospital, Beh Afarin Street, Karim Khan e Zand Avenue, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mehrdad Eftekhar MD

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School of medicine, Iran University of Medical Sciences, Hemat avenue, Tehran, Iran

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Tehran

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
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Department of physical medicine and rehabilitation, Iran University of Medical Sciences

Full name of responsible person
Samaneh Ghahramanpoori

Position
physical medicine and rehabilitation resident, Medical Doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty