Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Compare the effect of magnesium and vitamin B6 with pramipexole in improving the symptoms of restless leg syndrome patients referred to the clinic by University of Medical Sciences.

Protocol summary

Summary

The aim of this study was to investigate the role of magnesium and vitamin B6 in improving to the symptoms of restless leg syndrome in patients referred to clinics in Arak University of Medical Sciences. This study is a single-blind study. The subjects studied in this study. Based on the Petersburg Sleep Quality Scale and the IRLS Index, their disease is evaluated.We will examine the therapeutic effect of reducing the score of the two questionnaires after medication.Patients were randomly assigned to three groups of magnesium, vitamin B6, and control. In addition, on top of prescription drugs (primaxyxol), one tablet of 40 mg of vitamin B6 or 250 mg of magnesium oxide is also prescribed, but The control group, in addition to the medication, is given only placebo. After one and two months after the intervention, the results are evaluated.Significance of entry can be RLS history for 6 months, ages 15 to 50 years, and exit criteria may include a lack of willingness to continue the study, the occurrence of pregnancy during the study, and the side effects of the drug. The sample size of this study was 72 people Is taken.The time required to collect information for this study is nine months.If this study shows the therapeutic effect of magnesium and vitamin B6 in improving symptoms of restless leg syndrome, it could be used as an adjunct to treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070134806N1**
Registration date: **2017-07-27, 1396/05/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-27, 1396/05/05

Registrant information

Name
Ali Khanmohammadi
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 86 3405 2631
Email address
ali.khanmohammadi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2017-07-01, 1396/04/10

Expected recruitment end date

2018-03-30, 1397/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of magnesium and vitamin B6 with pramipexole in improving the symptoms of restless leg syndrome patients referred to the clinic by University of Medical Sciences.

Public title

Comparison of the effect of magnesium and vitamin B6

on the improvement of restless leg syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having a history of RLS for 6 months; Age 15 to 50 years; Lack of risk factors including pregnancy; Uremia; Diabetes and anemia; Lack of pregnancy; lack of renal impairment.Exclusion criteria: Unwillingness to continue the study; The occurrence of pregnancy during the study;The side effects of the drug.

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square, Taleghani Street.

City

Arak

Postal code

Approval date

2017-06-28, 1396/04/07

Ethics committee reference number

IR.ARAKMU.REC.1396.63

Health conditions studied

1

Description of health condition studied

Restless legs syndrome

ICD-10 code

G25.8

ICD-10 code description

Restless legs syndrome

Primary outcomes

1

Description

Improvement of sign restless leg syndrome

Timepoint

Befor, One & Two mounth after Intervention

Method of measurement

questionnaire of IRLS

Secondary outcomes

1

Description

Improve the quality of sleep

Timepoint

Befor, One & Two mounth after Intervention

Method of measurement

questionnaire of PSQ

Intervention groups

1

Description

For the first intervention group; Pramipexolel tablets, 75 mg oral, once a day for two months & Vitamin B6 tablets 40 mg oral, once a day for two month

Category

Treatment - Drugs

2

Description

For the second intervention group; Pramipexole 75 mg oral tablet, once a day for two months & Magnesium oxide 250 mg oral tablet, once a day for two months

Category

Treatment - Drugs

3

Description

For control group; Pramipexole 75 mg oral tablet, once a day for two months & Placebo oral tablet, once a day for two month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital

Full name of responsible person

Street address

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Ali Reza Rezai Ashtiani

Street address

Arak University of Medical Sciences, Basij Square, Taleghani Street

City

Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Ali Jadidi

Position

Master of nursing

Other areas of specialty/work

Street address

Arak University of Medical Sciences, Basij Square, Taleghani Street

City

Arak

Postal code

Phone

+98 86 3417 3508

Fax

Email

jadidi.ali83@yahoo.comJadidi@arakmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Ali Khan Mohammadi Hazaveh

Position

Bachelor of Nursing

Other areas of specialty/work

Street address

Arak University of Medical Sciences, Basij Square, Taleghani Street.

City

Arak

Postal code

Phone

+98 86 3417 3508

Fax

Email

Ali.khanmohammadi@arakmu.ac.iralikhan.nurse@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Seyyed Mohammad Aghaei Pour

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

00

Fax

Email

mohamadaqaee.nurse@gmail.com

Web page address

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