

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Oral Magnesium Therapy for Periodic Limb Movement Syndrome: a Randomized Clinical Trial

Protocol summary

Study aim

Effect of Oral Magnesium Therapy for Periodic Limb Movements in Sleep

Design

A randomised, blinded, placebo controlled clinical trial with a parallel group design of 14 patients in each group (total number of 28), randomized with Random numbers table

Settings and conduct

patients underwent polysomnography with periodic limb movements in sleep will enroll in the study and divide randomly in two groups, after evaluation of exclusion criteria and Informed consent. In the first group a 250 mg magnesium tablet will prescribe for 4 weeks. The second group will receive placebo. Patients will be blind to drugs. Then they will reassess with polysomnography for periodic limb movements in sleep and will be compared to pretreatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: periodic limb movements in polysomnography Exclusion criteria: decrease in ferritin level increase in blood urea nitrogen increase in creatinine pregnancy iron deficiency anemia

Intervention groups

Prescribing Oral Magnesium and Placebo

Main outcome variables

number of periodic limb movements in sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170128032249N2**

Registration date: **2019-06-16, 1398/03/26**

Registration timing: **prospective**

Last update: **2019-06-16, 1398/03/26**

Update count: **0**

Registration date

2019-06-16, 1398/03/26

Registrant information

Name

Zahra Banafsheh Alemohammad

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5567 7333

Email address

alemohammadz@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Oral Magnesium Therapy for Periodic Limb Movement Syndrome: a Randomized Clinical Trial

Public title

Oral Magnesium Therapy in Periodic Limb Movement Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

periodic limb movements in polysomnography

Exclusion criteria:

decrease in ferritin level increase in blood urea nitrogen
increase in creatinine pregnancy iron deficiency anemia

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization by Random Numbers Table

Blinding (investigator's opinion)

Single blinded

Blinding description

Blindness of Participants Regarding Main Drug or Placebo

Placebo

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

Tehran University of Medical Sciences, Ghods Ave., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-06-20, 1397/03/30

Ethics committee reference number

IR.TUMS.VCR.REC.1397.178

Health conditions studied

1

Description of health condition studied

periodic limb movements in sleep

ICD-10 code

G47.61

ICD-10 code description

Periodic limb movement disorder

Primary outcomes

1

Description

periodic limb movements in sleep

Timepoint

At the beginning of the study and 28 days after the start of oral magnesium

Method of measurement

polysomnography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: a 250 mg magnesium tablet will prescribe once a day for 4 weeks after a meal

Category

Treatment - Drugs

2

Description

Control group: a placebo tablet will prescribe once a day for 4 weeks after a meal

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sleep Clinic of Baharloo Hospital

Full name of responsible person

Zahra Banafsheh Alemohammad

Street address

Baharloo Hospital, Behdari St., Rahahan Sq.

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Web page address

<http://baharloohospital.tums.ac.ir/baharloo/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

sixth floor, Tehran University of Medical Sciences,
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1424456666

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Email

research@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Banafsheh Alemohammad

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Occupational Medicine

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Person responsible for updating data

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Email

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