Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of promipexol versus no treatment in migraine patients with restlessleg syndrome: a before after clinical trial

Protocol summary

Summary

Objectives: To assess the effect of promipexol versus no treatment in migraine patients with restless leg syndrome. Design: a before after clinical trial. Setting and conduct: The eligible migraine patients who will refer to Farshchian Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) The frequency of headache at least 4 times a month; (b) headache leads to dysfunction. Exclusion criteria: (a) breastfeeding and pregnancy; (b) contraindication of promipexol. Intervention group: Routine treatment plus promipexol 18 mg (on fourth of tablet) once a night and then increasing the dose gradually to a maximum of one tablet every night for 3 months. Control group: In comparison with before treatment. Primary outcome: Assessing the frequency of headache one, two, and three months after treatment using questionnaire. Secondary outcome: (a) assessing the nausea and vomiting one, two, and three months after treatment using questionnaire; (b) assessing the insomnia one, two, and three months after treatment using questionnaire; (c) assessing the dizziness one, two, and three months after treatment using questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506019014N63**
Registration date: **2015-06-06, 1394/03/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-06, 1394/03/16

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of promipexol versus no treatment in migraine patients with restlessleg syndrome: a before after clinical trial

Public title

Effect of promipexol versus no treatment in migraine patients with restlessleg syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) The frequency of headache at least 4 times a month; (b) headache leads to dysfunction.

Exclusion criteria: (a) breastfeeding and pregnancy; (b) contraindication of promipexol.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
Randomization: This is a before after trial without randomization. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Postal code
6517838695

Approval date
2015-04-11, 1394/01/22

Ethics committee reference number
D/P/16/35/9/42

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Assessing the frequency of headache

Timepoint
one, two, and three months after treatment .

Method of measurement
using questionnaire

Secondary outcomes

1

Description
assessing the dizziness

Timepoint
one, two, and three months after treatment

Method of measurement
using questionnaire

2

Description
assessing the insomnia

Timepoint
one, two, and three months after treatment

Method of measurement
using questionnaire

3

Description
assessing the nausea and vomiting

Timepoint
one, two, and three months after treatment

Method of measurement
using questionnaire

Intervention groups

1

Description
In comparison with before treatment

Category
N/A

2

Description
Routine treatment plus promipexol 18 mg (on fourth of tablet) once a night and then increasing the dose gradually to a maximum of one tablet every night for 3 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Afshin Afshari
Street address
Farshchian Hospital, Mirzadeh Eshghi Ave.
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research the Technology, Hamadan 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
Farshchian Hospital
Full name of responsible person
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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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