

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation effect of Propranolol and Pramipexole compared with Propranolol and placebo on treatment of Migrain headache in patients with Migraine and restless legs syndrome at the same time in patient referred to neurology clinic of Ahwaz Golestan hospital

Protocol summary

Summary

Objectives: Evaluation effect of Pramipexole in patients with Migraine and restless legs syndrome at the same time Design: Double blind randomized clinical trial Setting and conduct: The severity of RLS(in IRLLG basis), number and severity of Migrain attack, presence or absence of morning headaches and The use of painkillers in the past three months are questioned from patients. Patients will randomly divide into two groups And go under study Participants: Among patients with headache who Referred to neurology clinic of Ahwaz Golestan hospital, patient who have 15 to 50 years old and confirm their Migrain diagnosis with International Headache Society (IHS) criteria and have no history of treatment and they have symptoms of restless leg syndrome and consent to be enrolled in the study with consider this criteria: Main inclusion criteria: No pregnant weman: No menopause weman :No history of Alcohol or substance addiction :No history of cardiac block or bradycardia:No history of second cause for restless legs syndrome Main exclusion criteria: Patient who stop continuing the study in each reason; Patient who will be menopause or pregnant Intervention: One group will treat with Propranolol 20 mg twice a day and placebo two hour before sleep time and another group will treat with Propranolol 20 mg twice a day and Pramipexol 0.7 mg two hours before sleep time for three month . Main outcome measures: severity of Migrain base on Midas questionnaire

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022026166N1**

Registration date: **2016-08-31, 1395/06/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-31, 1395/06/10

Registrant information

Name

Farzaneh Karimian

Name of organization / entity

Ahwaz Jondishapour university of medical science

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Ahwaz Jundishapour university of medical science

Expected recruitment start date

2015-08-15, 1394/05/24

Expected recruitment end date

2016-05-13, 1395/02/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation effect of Propranolol and Pramipexole

compared with Propranolol and placebo on treatment of Migrain headache in patients with Migraine and restless legs syndrome at the same time in patient referred to neurology clinic of Ahwaz Golestan hospital

Public title

Evaluation effect of Pramipexole in patients with migraine and restless legs syndrome at the same time

Purpose

Treatment

Inclusion/Exclusion criteria

Main inclusion criteria: No pregnant weman! No menopause weman !No history of Alcohol or substance addiction !No history of cardiac block or bradycardia!No history of second cause for restless legs syndrome Main exclusion criteria: Patient who stop continuing the study in each reason; Patient who will be menopause or pregnant

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Morality committee of Ahwaz Jundishapour university of medical science and health services

Street address

Ahwaz Jundishapour university of medical science and health services, Farvardin boulevard, Golestan highway

City

Ahwaz

Postal code

Approval date

2015-08-15, 1394/05/24

Ethics committee reference number

IR.AJUMS.REC.1394.391

Health conditions studied

1

Description of health condition studied

Migrain, restless legs syndrome

ICD-10 code

G43, G26

ICD-10 code description

Migraine, Other extrapyramidal and movement disorders

Primary outcomes

1

Description

Severity of Miigrain

Timepoint

Start and after 3 months

Method of measurement

Midas questionnaire

2

Description

Severity of restless leg syndrome

Timepoint

Start and after 3 months

Method of measurement

IRLLG questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First group will treat with Propranolol 20 mg twice a day and placebo two hour before sleep time for three months

Category

Treatment - Drugs

2

Description

Second group will treat with Propranolol 20 mg twice a day and Pramipexol 0.7 mg two hours before sleep time for three months .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital clinic

Full name of responsible person

Farzaneh Karimian

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Golestan hospital**City**

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice chancellor for research of Ahwaz Jundishapour
university of medical science**Full name of responsible person**

Seid Ahmad hosseini

Street addressAhwaz Jundishapour university of medical science and
health services, Farvardin boulevard, Golestan
highway**City**

Ahwaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding sourceVice chancellor for research of Ahwaz Jundishapour
university of medical science**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**Ahwaz Jundishapour university of medical science and
health services**Full name of responsible person**

Farzaneh Karimian

Position

Resident

Other areas of specialty/work**Street address**Farvardin boulevard, Golestan highway, Ahwaz
Golestan hospital, Neurology department**City**

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**Person responsible for scientific
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Full name of responsible person

Shahram Rafi

Position

MD,PHD

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Position

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Iran

Phone

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Fax**Email****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