Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 questionary

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

Country

Iran (Islamic Republic of)

Phone

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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 questionary

2

Description
Severity of restless leg syndrome
Timepoint
Start and after 3 months
Method of measurement
IRLLG questionary

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
Street address
Farvardin boulevard، Golestan highway، Ahwaz
Golestan hospital
City
Ahwaz

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 address
Ahwaz Jundishapour university of medical science and health services، Farvardin boulevard، Golestan highway
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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 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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