

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between the effect of Rosuvastatin and Orlept (Sodium Valproate) in Decrease of migraine headaches

Protocol summary

Study aim

Comparison between the effect of Rosuvastatin and Orlept (Sodium Valproate) in Decrease of headaches attack in persons with Migraines

Design

Select people to be in each group will be permuted block randomization. To blind this study given special code to Each patient. Patients are randomly divided into two groups (Each group consists of 20 patients). These samples will be selected from patients referring to the department of neurology at hospital.

Settings and conduct

In this study, samples will be collected according to Goal Based. Patients are divided into two groups of parallel therapy and under therapy for 3 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria Patients Age between 15-55 years Have migraine headaches With or Without a up to 6months before this study Confirmation of the presence of migraine by the neurologist There are more than 4 months of attack Have two or more headache attacks over the past 3 month Those who have not received sodium valproate within the last six months Exclusion criteria Patients with mental illness Patients with systemic and background diseases such as diabetes, liver or malignant diseases Pregnant and Lactating women Desire to quit See incidence of complications

Intervention groups

Patients are randomly divided into two groups (Each group consists of 20 patients). Treatment in Group one received sodium valproate (500 mg) and Rosuvastatin (20 mg per day) for 12 weeks, and group two received 500 mg of sodium valproate (Orlept) per day at the same time.

Main outcome variables

Migraine Headaches

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180114038369N1**

Registration date: **2018-03-18, 1396/12/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-18, 1396/12/27**

Update count: **0**

Registration date

2018-03-18, 1396/12/27

Registrant information

Name

Reyhaneh Tabaraei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3612 2000

Email address

rtabarai@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-30, 1396/11/10

Expected recruitment end date

2018-04-30, 1397/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the effect of Rosuvastatin and Orlept (Sodium Valproate) in Decrease of migraine headaches

Public title

Comparison between the effect of Rosuvastatin and Orlept (Sodium Valproate) in Decrease of migraine headaches

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Those who have not received sodium valproate within the last six month. Have migraine headaches With or Without a up to 6 month before this study Confirmation of the presence of migraine by the neurologist There are more than 4 month of attack Have two or more headache attacks over the past 3 month

Exclusion criteria:

Patients with mental illness Patients with systemic and background diseases such as diabetes, liver or malignant diseases Pregnant and Lactating women Desire to quit of this study See incidence of complications

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will also be done using the permutated block randomization method

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind this study, each patient given a special code. Prescribing medicines in a double-blind manner, the medications are given to the patients by the supervisor of the hospital, in accordance with the codes prescribed in the package.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

Qom University of Medical Science and Health service, Saheli Ave, Qom

City

Qom

Province

Ghoum

Postal code

3716987366

Approval date

2018-01-02, 1396/10/12

Ethics committee reference number

Ir.Muq.Rec.1396.96

Health conditions studied

1

Description of health condition studied

Migraine headaches

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Migraine headache

Timepoint

Follow up these Patient will be done for 3 months.

Method of measurement

The severity of migraine headache is measured by the Visual Analogue Scale (VAS).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment in Group 1 using sodium valproate

Category

Treatment - Drugs

2

Description

Intervention group: Treatment in group two using rosuvastatin tablets

Category

Treatment - Drugs

Country of origin**Type of organization providing the funding**

Academic

Recruitment centers**1****Recruitment center****Name of recruitment center**

Qom Hospital

Full name of responsible person

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ghoum University of Medical Sciences

Full name of responsible person

Hossein Saghafi

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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

Ghoum 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

Person responsible for general inquiries**Contact****Name of organization / entity**

Ghoum University of Medical Sciences

Full name of responsible person

Reyhaneh Tabaraei

Position

Asistance Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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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