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 permutated 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
rtabaraii@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

Recruitment centers

1

Recruitment center
Name of recruitment center
Qom Hospital
Full name of responsible person
Reyhaneh Tabaraei
Street address
Qom
City
Qom
Province
Ghoum
Postal code
3716987366
Phone
+98 25 3612 2000
Email
rtabaraii@muq.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Hossein Saghafi
Street address
Qom
City
Qom
Province
Ghoum
Postal code
3716987366
Phone
+98 25 3107 1300
Email
rtabaraii@muq.ac.ir
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
Country of origin
Type of organization providing the funding
Academic

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
Street address
Saheli Ave.
City
Qom
Province
Ghoum
Postal code
3716987366
Phone
+98 25 3107 1300
Email
rtabaraii@muq.ac.ir

Person responsible for scientific 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
Street address
Saheli Ave.
City
Qom
Province
Ghoum
Postal code
3716987366
Phone
+98 25 3107 1300
Email
rtabaraii@muq.ac.ir

Person responsible for updating data

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
Street address
Saheli Ave.
City
Qom
Province
Ghoum
Postal code
3716987366
Phone
+98 25 3107 1300
Email
rtabaraii@muq.ac.ir

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