

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Aug 2026

Effect of Atorvastatin in Prophylaxis of Migraine Attacks in Patients with Classic Migraine

Protocol summary

Study aim

Study of the Effect of Atorvastatin on Prevention of Migraine Attacks

Design

This study is in Phase 3 clinical trials. Individuals include 68 patients with migraine based on the ICDH II diagnostic index. The entry of individuals into groups is completely randomized. Patients assigned blocking with using a randomized technique and with use foursome blocks divided into 2 groups of 34 Intervention and Control. given to Intervention Group Atorvastatin and Sodium Valproate, and to Control Group Sodium Valproate and placebo. Also patients who take sodium Valproate beforehand divided into two groups randomly, and received continues treatment. Information about the randomization of individuals is kept confidential by a person not involved in the study.

Settings and conduct

This is a randomized, triple-blind clinical trial with placebo and drug in Ahvaz. Patients in a period of at least one month to control the level of vitamin D3, entry and exit and control life style of education. After this period, patients will be treated. Visual Analog Scale (VAS) scale is used to measure the pain intensity and the data of the subjects is analyzed statistically. During the study, patients are regularly taking into account. Drug and Placebo are Completely Similar in Appearance and Packaging, and Patients Receiving Drug and Placebo , as well as Researchers and People who Collect and Analyze Data are Unaware of Their Nature.

Participants/Inclusion and exclusion criteria

Entry Criteria: aged over 18 years; having at least 4 migraine attacks per month; serum vitamin D3 levels are normal. Non-entry Criteria: Having chronic daily headaches; abuse drugs; having conditions requiring statins; coronary artery disease; peripheral vascular disease; diabetes; kidney disease; hypercalcemia; elderly; pregnancy

Intervention groups

The drug group (intervention) includes patients who receive Sodium Valproate and Atorvastatin. The placebo (control) group includes patients who receive Sodium Valproate and placebo.

Main outcome variables

Number of attacks; severity of attacks; patient satisfaction with treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180106038242N1**

Registration date: **2018-02-07, 1396/11/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-07, 1396/11/18**

Update count: **0**

Registration date

2018-02-07, 1396/11/18

Registrant information

Name

Reza Ganji

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3373 8380

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gangi-r@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Atorvastatin in Prophylaxis of Migraine Attacks in Patients with Classic Migraine

Public title
Effect of Atorvastatin in Prophylaxis of Migraine Attacks in Patients with Classic Migraine Compared to Standard Treatment Sodium Valproate

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 18 to 65 years Having at least 3 migraine attacks per month Patients who have fewer than three attacks per month, provided that they affect high-intensity attacks and the patient's life Have a normal serum level of vitamin D3 Patients with classical migraine
Exclusion criteria:
 Patients who do not sign a form of moral consent. Patients with chronic headaches (more than 15 attacks per month) Patients receiving Statin for other diseases Severe renal failure (GFR <30 ml / min) Creatine Kinase more than 3 times normal Liver enzymes more than twice the normal range The increase in liver enzymes during treatment is more than 3 times the normal Other patients who use drugs other than sodium valproate to treat their migraines and have their disease controlled or sodium valproate, and the disease is under control Pregnant women

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
The entry of individuals into these groups is done in a completely randomized way. Patients were randomly assigned to a 1: 1 ratio,are blocking with using a randomized technique and with use foursome blocks divided into 2 groups of 34 patients and placebo.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Drug and Placebo are Completely Similar in Appearance and Packaging, and Patients Receiving Drug and Placebo , as well as Researchers and People who Collect and Analyze Data are Unaware of Their Nature.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Ahvaz University of Medical Sciences
Street address
 Ahvaz University of Medical Sciences, Golestan Blvd, Golestan
City
 Ahvaz
Province
 Khuzestan
Postal code
 6135815751
Approval date
 2017-10-28, 1396/08/06
Ethics committee reference number
 IR.AJUMS.IREC.1396.724

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Severity of migraine pain according to the Visual Analogue Scale (VAS)

Timepoint
The measurement of pain intensity based on the Visual Analogue Scale (VAS) at the beginning of the study (before the intervention) and And one day after the intervention(4 weeks after the onset of Atorvastatin)

Method of measurement
Visual Analogue Scale (VAS)

2

Description

The Rate of Migraine Attacks

Timepoint

The question of the history of migraine attacks in a 8-week interval

Method of measurement

Ask The Patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group received daily 200 mg of sodium valproate (a 200 mg tablet of Iran Najo Pharmaceutical Company[Iran]) and 20 mg of Atorvastatin (a 20 mg tablet of Shafa pharmaceutical company [Iran]) for four weeks.

Category

Prevention

2

Description

Control group: Received 200 mg of Sodium Valproate (200 mg per day) and placebo tablets similar to Atorvastatin.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Sayah Bargard's Office

Full name of responsible person

Mehdi Sayah

Street address

Dr. Sayah Bargard's Office, Eastern Mihaan St, Kianpars

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences Research Assistance

Full name of responsible person

Mohammad Badavi

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz University of Medical Sciences Research Assistance

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

Ahvaz University of Medical Sciences

Full name of responsible person

Reza Ganji

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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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