Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Khouzestan

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
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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
Street address
Ahvaz University of Medical Sciences, Golestan Blvd, Golestan
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Fax
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Email
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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

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Position
Associate professor

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Person responsible for updating data

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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