

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the effectiveness of Atorvastatin and Nortriptyline in prophylaxis of migraine attacks in patients with classic migraine compared to standard treatment Nortriptyline: a randomized triple blind controlled clinical trial

#### Protocol summary

##### Study aim

Evaluation of the efficacy of atorvastatin and nortriptyline compared with placebo and nortriptyline in controlling migraine attacks

##### Design

Clinical trial with control group, with parallel groups, blind and randomized trials

##### Settings and conduct

Sample selection at Imam Mohammad Bagher Clinic of Bam and Clinic of Afshar Hospital in Yazd city with satisfaction and knowledge of patients and considering the conditions for entering the study is done.

##### Participants/Inclusion and exclusion criteria

Only patients aged 18 to 65 years with a migraine diagnosis based on the IHS criteria of at least six months before the start of the study, and normal levels of vitamin D3 (greater than 30ng / mL) will be included. New patient cases that are scheduled to be studied should have at least 3 migraine attacks per month. Patients with fewer than three attacks per month will be included in the study, provided that the attacks are highly intense and affect the patient's life.

##### Intervention groups

The efficacy of atorvastatin in combination with nortriptyline in decreasing the severity and severity of migraine attacks and improving the quality of life of patients and not taking atorvastatin and prescribing nortriptyline alone in the control group

##### Main outcome variables

the severity of migraine attacks; the frequency of migraine attacks; quality of life; side effects of treatment.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190620043953N2**

Registration date: **2020-04-02, 1399/01/14**

Registration timing: **retrospective**

Last update: **2020-04-02, 1399/01/14**

Update count: **0**

##### Registration date

2020-04-02, 1399/01/14

##### Registrant information

##### Name

Amir Sharafat

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3828 6667

##### Email address

dr.sharafat.amir@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-06, 1398/04/15

##### Expected recruitment end date

2019-09-06, 1398/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effectiveness of Atorvastatin and Nortriptyline in prophylaxis of migraine attacks in patients with classic migraine compared to standard treatment Nortriptyline: a randomized triple blind controlled clinical trial

**Public title**

Study of the effect of statins on migraine

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18 to 65 years old Having at least 3 migraine attacks per month Patients who have fewer than three attacks per month Provided that the severity of the attacks is high and affects the person's life. Having a normal serum level of vitamin D3 Sufficient literacy to understand the study, use of medication and possible side effects

**Exclusion criteria:**

Patients who do not sign a moral consent form. Patients with chronic headaches (more than 15 attacks per month). Patients receiving statin due to other diseases, such as diabetes, dyslipidemia, coronary artery disease, peripheral vascular disease, etc. Patients with severe renal insufficiency (GFR <30 ml / min) Failure to cooperate to continue treatment

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

All patients referred to Khatamolania neurology clinic who fulfilled criteria for study at first are marked by a number and then assigned in two intervention and control groups alternatively by chart of random numbers. Selection of patient for first group is by lottery.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants in the researchers plan and researcher committee are kept blind to the study groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary IDs**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of yazd University of Medical Sciences

**Street address**

Alam Square, Shahid Sadoughi Pharmaceutical Faculty, Yazd

**City**

yazd

**Province**

Yazd

**Postal code**

1111111111

**Approval date**

2019-11-03, 1398/08/12

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1398.197

**Health conditions studied****1****Description of health condition studied**

migraine headaches

**ICD-10 code**

G43

**ICD-10 code description**

Migraine

**Primary outcomes****1****Description**

Frequency of migraine headache attacks

**Timepoint**

24 weeks after the start of the study

**Method of measurement**

Number of attacks in a month based on patient statements

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Management group: In this group Atorvastatin 40mg tablets from Abidi company, once a day and Nortriptyline 25mg tablets from Abidi company, once a day for 24 days will be used and after 4, 14 and 24 week use a visit.

**Category**

Prevention

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### Description

Control group: Atorvastatin placebo tablets; from Yazd University of Medical Sciences laboratory, once daily and Nortriptyline 25mg tablets from Abidi company once a day, for 24 days will be used your and after 4, 14 and 24 week use a visit and no extra work

### Category

Prevention

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Khatam Al-Anbia Super Speciality Clinic

#### Full name of responsible person

Amir Sharafat

#### Street address

Taleghani Blvd, Yazd

#### City

Yazd

#### Province

Yazd

#### Postal code

4364657888

#### Phone

+98 35 3733 0122

#### Fax

+98 35 3726 3154

#### Email

cllinik@ssu.ac.ir

#### Web page address

<http://www.ssu.ac.ir/cms/index.php?id=638>

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Yazd University of Medical Sciences

#### Full name of responsible person

Masoud Mirzaei

#### Street address

Bahonar Ave

#### City

Yazd

#### Province

Yazd

#### Postal code

9856783459

#### Phone

+98 35 3724 0171

#### Fax

+98 35 3724 0171

#### Email

mmirzaei@ssu.ac.ir

#### Web page address

[https://web.ssu.ac.ir/Index.aspx?page\\_=form&lang=1](https://web.ssu.ac.ir/Index.aspx?page_=form&lang=1)

&sub=21&tempname=pajoheshi&PageID=515&isPopUp=False

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Yazd 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

Yazd University of Medical Sciences

#### Full name of responsible person

Roya Rahmany

#### Position

Student

#### Latest degree

A Level or less

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

Adab Ave

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#### Province

Yazd

#### Postal code

8915811113

#### Phone

+98 35 3830 0940

#### Email

royarahmany9@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Yazd University of Medical Sciences

#### Full name of responsible person

Amir Sharafat

#### Position

Specialist

#### Latest degree

Specialist

#### Other areas of specialty/work

Medical Education

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sherafat.a@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Roya Rahmany  
**Position**  
Student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
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**City**  
Yazd  
**Province**  
Yazd  
**Postal code**  
8915811113  
**Phone**  
+98 35 3830 0940  
**Email**  
royarahmany9@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

All collected deidentified of IPD

### When the data will become available and for how long

Starting 6 month after publication

### To whom data/document is available

Only available for people working in academic institutions

### Under which criteria data/document could be used

Only for scientific research

### From where data/document is obtainable

email address of roya rahmany(student of pharmacy in shahid sadoughi univercity of yazd):  
royarahmany9@gmail.com

### What processes are involved for a request to access data/document

Documents will be send 2weeks after direct request by email to the corresponding author

### Comments