

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study of the therapeutic effects of Atomoxetine in comparison with placebo on reducing the incidence of symptoms in patients with recurrent vasovagal syncope;

#### Protocol summary

##### Study aim

Study of therapeutic effects of Atomoxetine in reducing the incidence of symptoms in patients with recurrent vasovagal syncope

##### Design

This study is a double-blind placebo-controlled randomized clinical trial.

##### Settings and conduct

In this study, patients will be recruited from referrals to the specialized syncope clinic of Tehran Heart Center. Eligible participants will be randomized to 2 parallel groups with a 1:1 ratio: 1) Standard treatment plus atomoxetine. 2) Standard treatment plus identical-looking placebo. Medications will be given to patients in sequentially numbered opaque sealed envelopes. This is a double-blind randomized clinical trial in which the patients and the investigators will be blinded to the randomized intervention. Follow-up visits will be done on month 1 and 3.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who come to the Tehran Heart Center with a complaint of syncope or pre-syncope with the clinical diagnosis of vasovagal syncope or have undergone tilt test, if needed, and experienced at least 3 syncopal episodes in the past 3 months. Exclusion criteria: Age under 10 or over 70 years old History of uncontrolled blood pressure History of structural heart disease History of epilepsy History of closed angle glaucoma History of diabetes mellitus History of coronary artery disease Ejection fraction < 50% Use of monoamine oxidase inhibitors (MAOIs) Use of selective serotonin reuptake inhibitors (SSRIs) Use of anticonvulsants

##### Intervention groups

Intervention group: Administration of Atomoxetine with a dose of 20 mg per day for 2 weeks and 40 mg per day for another 2 weeks if tolerated Control group: Receive

placebo with the above command

##### Main outcome variables

The number of (pre-)syncopal episodes on month 1 and 3.

#### General information

##### Reason for update

Completion and modification of the protocol of the study according to the setting of the recruitment

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180125038507N1**

Registration date: **2018-08-03, 1397/05/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-24, 1398/10/03**

Update count: **1**

##### Registration date

2018-08-03, 1397/05/12

##### Registrant information

##### Name

Masih Tajdini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8802 9640

##### Email address

mtajdini@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2019-07-23, 1398/05/01  
**Actual recruitment start date**  
2018-07-25, 1397/05/03  
**Actual recruitment end date**  
2019-07-23, 1398/05/01  
**Trial completion date**  
2019-10-23, 1398/08/01

#### Scientific title

Study of the therapeutic effects of Atomoxetine in comparison with placebo on reducing the incidence of symptoms in patients with recurrent vasovagal syncope;

#### Public title

Study of therapeutic effects of Atomoxetin in reducing the symptoms of patients with recurrent vasovagal syncope

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients who come to the Tehran Heart Center with a complaint of syncope or pre-syncope with the clinical diagnosis of vasovagal syncope or have undergone tilt test, if needed, and experienced at least 3 syncopal episodes in the past 3 months.

##### Exclusion criteria:

Age under 10 or over 70 years old  
History of uncontrolled blood pressure  
History of structural heart disease  
History of epilepsy  
History of closed angle glaucoma  
History of diabetes mellitus  
History of coronary artery disease  
Ejection fraction < 50%  
Use of monoamine oxidase inhibitors (MAOIs)  
Use of selective serotonin reuptake inhibitors (SSRIs)  
Use of anticonvulsants

#### Age

From **10 years** old to **70 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator

#### Sample size

Target sample size: **50**

Actual sample size reached: **46**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients are randomized and divided into two groups based on permutation blocks and they fall into one of the medication and placebo groups.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

This is a double-blind study. Both patients and investigators were blinded to the medication and placebo.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

School of Medicine- Tehran University of Medical Sciences

##### Street address

North kargar street, Tehran heart center

##### City

Tehran

##### Province

Tehran

##### Postal code

1411713138

#### Approval date

2018-07-25, 1397/05/03

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.273

## Health conditions studied

### 1

#### Description of health condition studied

Syncope

#### ICD-10 code

R55

#### ICD-10 code description

Syncope and collapse

## Primary outcomes

### 1

#### Description

The number of (pre-)syncopal episodes

#### Timepoint

Follow-up visit at month 1 and 3

#### Method of measurement

Based on history and physical exam

## Secondary outcomes

### 1

#### Description

Anxiety

#### Timepoint

Follow-up visit on month 3

#### Method of measurement

Hospital Anxiety and Depression Scale Questionnaire

## 2

### **Description**

Depression

### **Timepoint**

Follow-up visit on month 3

### **Method of measurement**

Hospital Anxiety and Depression Scale Questionnaire

## 3

### **Description**

Physical quality of life

### **Timepoint**

Follow-up visit on month 3

### **Method of measurement**

36-Item Short Form Survey Questionnaire

## 4

### **Description**

Mental quality of life

### **Timepoint**

Follow-up visit on month 3

### **Method of measurement**

36-Item Short Form Survey Questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention group: Atomoxetine 20 mg daily, taken orally, for 2 weeks and 40 mg daily for another 2 weeks, if tolerated. The pills will be sealed in 2 envelopes for each 2-week period: 14 pills (20 mg) in envelope A and 14 pills (40 mg) in envelope B.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Placebo pills are administered orally daily for a period of 4 weeks in envelopes A and B as discussed earlier. Placebos will be produced by the pharmacy department of Tehran University of Medical Sciences.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Tehran Heart Center

##### **Full name of responsible person**

Masih Tajdini

##### **Street address**

North kargar stret

##### **City**

tehran

##### **Province**

Tehran

##### **Postal code**

1411713138

##### **Phone**

+98 21 8802 9600

##### **Email**

drmasih84@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Masih Tajdini

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North kargar street

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##### **Province**

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##### **Email**

drmasih84@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

#### **Full name of responsible person**

Masih Tajdini

#### **Position**

Assistant professor of cardiology

#### **Latest degree**

Specialist

#### **Other areas of specialty/work**

Cardiology  
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North kargar street  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Ali Bozorgi  
**Position**  
Assistant professor of cardiology  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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saeedtofighi69@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Saeed Tofighi  
**Position**

Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Cardiology  
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Tehran  
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**Email**  
Saeedtofighi69@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

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

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

All data will be published

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

2019

### To whom data/document is available

All

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

All

### From where data/document is obtainable

Dr Masih Tajdini

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

Appointment

### Comments