

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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 Atomoxtein 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

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1411713138

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Email

drmasih84@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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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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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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
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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