

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Prospective Evaluation of the Midodrine Efficacy in the Treatment of Vasovagal Syncope: A Randomized Placebo-Controlled Study

#### Protocol summary

##### Summary

The aim of this study is to compare efficacy of Midodrine in the treatment of vasovagal syncope. Patient who had at least one episode of syncope during previous 6-month period and a positive tilt-table test are included in the study. Patients are excluded if they had other causes of syncope; cardiovascular and /or systemic disease; systolic blood pressure >150 mmHg or diastolic blood pressure >95 mmHg; thyrotoxicosis; renal failure; pheochromocytoma. During five years, a total of 100 patients are randomly allocated to treatment with Midodrine or placebo. Treatment drug are given at a starting dose of 5 mg three times a day and increased up to a dose of 10 mg three times a day if required. Patients are followed every week for 3 weeks and every 2 months for 12 months. Primary outcome is frequency of syncope recurrence 6-month and one year after study. Secondary outcomes are satisfaction score and quality of life which will be measured 6-month and one year after study.

#### General information

##### Acronym

MVP-VVS

##### IRCT registration information

IRCT registration number: **IRCT138803061965N1**

Registration date: **2009-09-15, 1388/06/24**

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

Last update:

Update count: **0**

##### Registration date

2009-09-15, 1388/06/24

##### Registrant information

###### Name

Majid Haghjoo

###### Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2392 2163

###### Email address

majid.haghjoo@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Rajaie Cardiovascular Medical and Research Center

##### Expected recruitment start date

2006-07-14, 1385/04/23

##### Expected recruitment end date

2011-12-31, 1390/10/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Prospective Evaluation of the Midodrine Efficacy in the Treatment of Vasovagal Syncope: A Randomized Placebo-Controlled Study

##### Public title

Midodrine Versus Placebo in VasoVagal Syncope

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: (1) a frequency of at least one episode of syncope during previous 6-month and (2) a positive head-up tilt test. Exclusion criteria: (1) other causes of syncope; (2) cardiovascular and /or systemic disease; or (3) systolic blood pressure >150 mmHg or diastolic blood pressure >95 mmHg; or (4) thyrotoxicosis; or (5) renal failure; or (6) pheochromocytoma.

##### Age

From **15 years** old to **80 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Rajaie Cardiovascular Medical and Research Center

**Street address**

Rajaie Cardiovascular Medical and Research Center, Melklat Park, Vali-e-Asr Steet

**City**

Tehran

**Postal code**

1996911151

**Approval date**

2006-07-14, 1385/04/23

**Ethics committee reference number**

86/13

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

Vasovagal syncope

**ICD-10 code**

R55

**ICD-10 code description**

Syncope and collapse

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

Syncope recurrence

**Timepoint**

6-monthe and one year after treatment

**Method of measurement**

History

**Secondary outcomes****1****Description**

Satisfaction score

**Timepoint**

6-month and one year after treatment

**Method of measurement**

History (score 0=no response, score 6=excellent response)

**2****Description**

Quality of life

**Timepoint**

6-month and one year after treatment

**Method of measurement**

Endicott quality of life questionnaire

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

Midodrine 5 mg tid if neccessary 10 mg tid for one year

**Category**

Treatment - Drugs

**2****Description**

Placebo 5 mg tid if neccessary 10 mg tid for one year

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rajaie Cardiovascular Medical and Research Center

**Full name of responsible person**

Dr. Majid Haghjoo

**Street address**

Department of Pacemaker and Electrophysiology, Rajaie Cardiovascular Medical and Research Center, Mellat Park, Vali-e-Asr Street

**City**

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**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Research department of Rajaie Cardiovascular  
Medical and Research Center

**Full name of responsible person**

Dr. Avisa Tabib

**Street address**

Research department of Rajaie Cardiovascular  
Medical and Research Center, Mellat Park, Vali-e-Asr  
Street

**City**

Tehran

**Grant name****Grant code / Reference number**

86/13

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

Yes

**Title of funding source**

Research department of Rajaie Cardiovascular Medical  
and Research Center

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

### Person responsible for general inquiries

**Contact****Name of organization / entity**

Rajaie Cardiovascular Medical and Research Center

**Full name of responsible person**

Dr. Human Bakhshandeh

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

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### Person responsible for scientific inquiries

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Department of Pacemaker and Electrophysiology,  
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Associate Professor

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<http://www.rhc.ac.ir/DEPARTMENT/CARDIOLOGY/ELECTROPHYSIOLOGY/index.asp>

### Person responsible for updating data

**Contact**

### Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*