

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Comparison of Ivabradine effect versus placebo on ventricular rate in patients with non-paroxysmal atrial fibrillation under standard medical treatment

#### Protocol summary

##### Study aim

Evaluation of Ivabradine effect on ventricular rate in non-paroxysmal atrial fibrillation patients

##### Design

Two arm parallel group randomized trial with blinded post treatment care and outcomes assessment

##### Settings and conduct

Non-paroxysmal atrial fibrillation patients with ventricular rate of more than 70 , referred to the Loghman Hospital in Tehran who are eligible for the trial , randomized in to Ivabradine and placebo group.24 hours heart rhythm monitoring is performed before and after one month of intervention. Non of Patients or researchers or outcome assessors or statistical analyzers know who received the medication or placebo.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria Non-paroxysmal atrial fibrillation at randomization, with no prospect of cardioversion, antiarrhythmic treatment with group I or III drugs, or pulmonary vein ablation Beta-blocker or nondihydropyridine calcium channel blocker or digoxin therapy at the maximum dose recommended for or tolerated by the patient ventricular rate of more than 70 Be able to voluntarily give informed consent Exclusion criteria Medical causes that explain poor heart rate control: fever, anemia, hyperthyroidism ,etc patients with a known contraindication to Ivabradine Valve disease requiring surgical or percutaneous repair Impossibility to attend the visits scheduled in the protocol

##### Intervention groups

Non-paroxysmal atrial fibrillation patients with ventricular rate of more than 70

##### Main outcome variables

Mean 24 hours ventricular rate before and one month after intervention Mean daytime ventricular rate before and one month after intervention Mean night time

ventricular rate before and one month after intervention

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191230045950N2**

Registration date: **2022-04-10, 1401/01/21**

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

Last update: **2022-04-10, 1401/01/21**

Update count: **0**

##### Registration date

2022-04-10, 1401/01/21

##### Registrant information

##### Name

Seyede houra Yeganegi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3333 3881

##### Email address

sarvenaz\_yeganegi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-20, 1400/12/01

##### Expected recruitment end date

2023-02-20, 1401/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of Ivabradine effect versus placebo on ventricular rate in patients with non-paroxysmal atrial fibrillation under standard medical treatment

**Public title**

Ivabradine effect on ventricular rate in non-paroxysmal atrial fibrillation patients

**Purpose**

Treatment

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

Non-paroxysmal atrial fibrillation at randomization, with no prospect of cardioversion, anti arrhythmic treatment with group I or III drugs, or pulmonary vein ablation Beta-blocker or nondihydropyridine calcium channel blocker or digoxin therapy at the maximum dose recommended for or tolerated by the patient Ventricular rate of more than 70 Be able to voluntarily give informed consent

**Exclusion criteria:**

Medical causes that explain poor heart rate control: fever, anemia, hyperthyroidism ,etc Patients with a known contraindication to Ivabradine Valve disease requiring surgical or percutaneous repair Impossibility to attend the visits scheduled in the protocol

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The simple randomization method will be done via random number table ,individually, and each patient have her/his own code. The first 50 extracted numbers from 100, (for example numbers 19, 07,02, and 20, ...) , will be placed in the drug receiving group, and the rest, (for example, 01,03,05,06,13 , ...) in the placebo group. Then, by referring to the clinic, patients who are eligible for trial will be assessed in the order of entry number based on the framework specified in the target groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients do not know whether they have received medication or a placebo Researchers, outcome assessors, and statistical analyzers are not aware of which patients received the Ivabradine or placebo. .

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of Shahid Beheshti university of Medical Sciences

**Street address**

7th Floor, Bldg No.2 Shahid Beheshti University of Medical Sciences, Aarabi Ave, Daneshjoo Blvd, Velenjak, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

19839-63113

**Approval date**

2022-02-20, 1400/12/01

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1400.1071

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

Atrial fibrillation

**ICD-10 code**

I48.1

**ICD-10 code description**

Persistent atrial fibrillation

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

Ventricular rate in non-paroxysmal atrial fibrillation patients

**Timepoint**

Before and one month after intervention

**Method of measurement**

24 hours ambulatory heart rhythm monitoring

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

Mean daytime ventricular rate

**Timepoint**

Before and one month after intervention

**Method of measurement**

24 hours ambulatory heart rhythm monitoring

**2****Description**

Mean night time ventricular rate

**Timepoint**

Before and one month after intervention

**Method of measurement**

24 hours ambulatory heart rhythm monitoring

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

Intervention group: Patients in this group are prescribed Ivabradine at a dose of 5 mg twice a day (manufactured by Kobel Daroo Company) for one month. 24 hours ambulatory heart rhythm monitoring is performed before and after one month of treatment.

**Category**

Treatment - Drugs

**2****Description**

Control group: Patients in this group receive a placebo twice a day for one month. 24 hours ambulatory heart rhythm monitoring is performed before and one month after receiving the placebo

**Category**

Placebo

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

Loghman Hakim hospital

**Full name of responsible person**

Maryam Taherkhani

**Street address**

1th Floor, Bldg No.4 Loghman Hakim hospital,  
Makhsos Ave. , south kargar Ave.

**City**

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**Province**

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**Phone**

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**Email**

dr\_taherkhani2004@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

7th Floor, Bldg No.2 Shahid Beheshti University of  
Medical Sciences, Aarabi Ave, Daneshjoo Blvd,  
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zarghi@sbmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyede Houra Yeganegi

**Position**

Non-faculty specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Cardiology

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Maryam Taherkhani

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyede Houra Yeganegi

**Position**

Non-faculty specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Cardiology

**Street address**1th Floor, Bldg No.4 Loghman Hakim hospital,  
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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