

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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+98 28 3333 3881

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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.

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

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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

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 updating data

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Specialist
Other areas of specialty/work
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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