Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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)

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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 fibrilation

ICD-10 code
I48.1

ICD-10 code description
Persistent atrial fibrillation

Primary outcomes

1

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