Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the clinical efficacy of adding Ivabradine to the standard treatment in reducing the frequency of premature atrial complexes (PAC) in ECG holter comparing to the standard treatment , in patients with symptomatic frequent premature atrial complexes (PAC)

Protocol summary

Study aim
Determining the clinical efficacy of Ivabradine in reducing the frequency of PAC in ECG holter comparing to the standard treatment , in patients with symptomatic frequent PACs

Design
The study is a randomized clinical trial which will be single blinded and single center. Randomization will be done by the method of permuted block with randomized blocks of double, quadruple and sextet. For complying the allocation concealment, a web based method will be used.

Settings and conduct
This study will be done at Tehran Heart center, where the selected patients will be referred to electrophysiology clinic to enter study after being aware of all aspects of it. They use the selected treatment depending to the group they are joined, and at the 12th day of treatment, will undergo a 24-hourECG holter. Then the holter will be reviewed and the patients will be visited for the second time.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Ages between 18-75 years - PAC frequency in ECG holter between 5-10 % (average of 8% total heart beats). - The ability to understand and sign the letter of satisfaction Exclusion criteria: - History of using Ivabradine during last 2 months - Cardiovascular disorders - Congenital long QT or QT>500 msec at the beginning of study - using drugs with major interactions with Ivabradine - Pregnant or lactating patients - Advanced liver disease - AF rhythm.

Intervention groups
Patients referring to Tehran Heart Center clinic which have PAC frequency of 5-10% (about 8%) in 24-hour ECG holter. Two groups of 50 patients will participate in this study, that one of them will receive Ivabradine plus standard treatment for PAC (Metoprolol 25 mg po BD), while the other group will only receive the standard treatment.

Main outcome variables
Frequency of PAC in 24 hours ECG holter Symptoms of patients with symptomatic frequent PACs

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230618058519N1**
Registration date: **2023-08-16, 1402/05/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-16, 1402/05/25**
Update count: **0**

Registration date
2023-08-16, 1402/05/25

Registrant information

Name
Layla Nematipour

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 2205 5676

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2024-07-05, 1403/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the clinical efficacy of adding Ivabradine to the standard treatment in reducing the frequency of premature atrial complexes (PAC) in ECG holter comparing to the standard treatment , in patients with symptomatic frequent premature atrial complexes (PAC)

Public title

Evaluating the efficacy of Ivabradine in reducing the frequency of PAC , in patients with symptomatic frequent PACs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient in ages between 18-75 years. PAC frequency in ECG holter be between 5-10 % (average of 8%). Patients who have the ability to understand and sign the letter of satisfaction.

Exclusion criteria:

Patient have the history of using Ivabradine during last 2 months. Patients having cardiovascular disorders. Patients having congenital long QT or QT>500 msec at the beginning of study. using drugs with reducing heart rate effect, which have major interactions with Ivabradine. Patients whom are pregnant or lactating or tending to become pregnant. Patients suffering from advanced liver disease (class C of Child-Pugh score). Patient having the history of using Ivabradine, whom has had discontinued Ivabradine because of adverse effects. Patient having AF rhythm.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The study is a randomized clinical trial which will be single center. Randomization will be done by the method of permuted block with randomized blocks of double, quadruple and sextet. For complying the allocation concealment, a web based method will be used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-Tehran University of Medical Sciences

Street address

Keshavarz Blvd, Intersection of Qods Ave

City

Tehran

Province

Tehran

Postal code

1416633591

Approval date

2023-07-15, 1402/04/24

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.232

Health conditions studied

1

Description of health condition studied

Frequent premature atrial complex (PAC)

ICD-10 code

I49.1

ICD-10 code description

Atrial premature depolarization

Primary outcomes

1

Description

Frequency of PAC in 24 hours ECG holter

Timepoint

To understand the effect of Ivabradine on reducing the frequency of PAC, further holter will be done on 12th day of study for 24 hours.

Method of measurement

ECG holter

Secondary outcomes

1

Description

Rate of reduction in PAC frequency in ECG holter

Timepoint
To understand the effect of Ivabradine on reducing the frequency of PAC, further holter will be done on 12th day of study for 24 hours.
Method of measurement
24 hours ECG holter

2

Description
Symptoms of patients with symptomatic frequent PACs
Timepoint
To understand the effect of Ivabradine on reducing the frequency of PAC, further holter will be done on 12th day of study for 24 hours.
Method of measurement
24 hours ECG holter

Intervention groups

1

Description
Intervention group: Patients in intervention group use Ivabradine 5mg twice daily for 2 weeks. All of the patients in both groups, receive metoprolol 25mg BID as the standard treatment.
Category
Treatment - Drugs

2

Description
Control group: In control group patients only use the standard treatment as metoprolol 25mg BID for 2 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran heart center
Full name of responsible person
Mr Dr Farzad Masoudkabir
Street address
Tehran heart center, corner of the Jalaal-Al-Ahmad expressway, North Kaargar Ave.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran heart center
Full name of responsible person
Dr Farzad Masoudkabir
Street address
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Email
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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 heart center
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 heart center
Full name of responsible person
Dr Layla Nematipour
Position
Cardiology resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
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Person responsible for scientific inquiries

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Position
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Latest degree
Medical doctor

Other areas of specialty/work
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Person responsible for updating data

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Position
Cardiology resident

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Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information is 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