

# 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-hour ECG 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2205 5676

##### Email address

l.nematipour@gmail.com

##### 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

Tehran

#### Province

Tehran

#### Postal code

13138-14117

#### Phone

+98 21 8802 9600

#### Email

thc@tums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran heart center

#### Full name of responsible person

Dr Farzad Masoudkabir

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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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Tehran Heart Henter, Corner of Jalaal-Al-Ahmad Expressway, North Kaargar Ave.

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**Phone**

+98 21 8802 9600

**Email**

l.nematipour@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Layla Nematipour

**Position**

Cardiology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Layla Nematipour

**Position**

Cardiology resident

**Latest degree**

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