

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Investigating the Effect of Ivabradine Drug on Controlling the Ventricular Response in Atrial Fibrillation

#### Protocol summary

##### Study aim

Investigating the effect of ivabradine on controlling the ventricular response of atrial fibrillation

##### Design

In this study, G\*Power software is used to calculate the sample size. The variable investigated in this study is a quantitative variable and the measurements will be done before the start of the treatment and one month after the start of the treatment. 30 patients will be examined. In this research, there is no need for randomization and blinding.

##### Settings and conduct

The present study will be conducted on patients with stable and permanent AF referred to Imam Khomeini Educational-treatment Hospital, Ahvaz.

##### Participants/Inclusion and exclusion criteria

- In order to enter this study, patients must have a resting heart rate of more than 100 beats per minute, while confirming that they are suffering from permanent or persistent AF in the initial examinations, and the previous medications have no effect on improving their conditions. -Patients with conditions: lack of consent to start or continue treatment, people under 18 years of age, pregnant women, women who breastfeed their children, patients with acute liver and kidney failure, unstable vital signs, Patients with uncontrolled blood pressure and patients who show acute side effects during treatment will be excluded from the study.

##### Intervention groups

In this research, an attempt will be made to investigate the effect of one month's use of ivabradine at a dose of 5 mg twice a day in controlling the ventricular response of patients with permanent and persistent AF.

##### Main outcome variables

Heart beat; Ventricular response

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240207060933N1**  
Registration date: **2024-02-14, 1402/11/25**  
Registration timing: **prospective**

Last update: **2024-02-14, 1402/11/25**

Update count: **0**

##### Registration date

2024-02-14, 1402/11/25

##### Registrant information

##### Name

Yasaman Asadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3311 0000

##### Email address

yasaman199271@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-03-20, 1403/01/01

##### Expected recruitment end date

2025-03-19, 1403/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the Effect of Ivabradine Drug on Controlling the Ventricular Response in Atrial Fibrillation

## Public title

Investigating the Effect of Ivabradine Drug on Controlling the Ventricular Response in Atrial Fibrillation

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with permanent or persistent AF Heart rate greater than 100 beats per minute at rest.

### Exclusion criteria:

Age less than 18 years Pregnant women Women who breastfeed their children Patients with acute liver and kidney failure Lack of consent to start or continue the treatment process Patients with uncontrolled blood pressure

## Age

From **18 years** old to **90 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences

##### Street address

Golestan blv

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6135715794

#### Approval date

2024-02-07, 1402/11/18

#### Ethics committee reference number

IR.AJUMS.REC.1402.626

## Health conditions studied

### 1

#### Description of health condition studied

Atrial fibrillation

#### ICD-10 code

I48

#### ICD-10 code description

Atrial fibrillation and flutter

## Primary outcomes

### 1

#### Description

Ventricular Response

#### Timepoint

one month

#### Method of measurement

ECG Holter

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: One month's use of ivabradine at a dose of 5 mg twice a day

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam khomeini hospital

##### Full name of responsible person

Babak Payami

##### Street address

Azadegan street

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6193673166

##### Phone

+98 61 2222 1144

##### Email

hemam@ajums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mehrnoush Zaker kish

**Street address**

Golestan blv

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

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**Phone**

+98 61 3373 8383

**Email**

itc@ajums.ac.ir

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Babak Payami

**Position**

assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

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### Person responsible for scientific inquiries

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**Position**

assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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### Person responsible for updating data

**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Yasaman Asadi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Cardiology

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**Postal code**

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**Phone**

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**Fax****Email**

Yasaman199271@yahoo.com

### 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**

Not applicable

**Data Dictionary**

Not applicable