

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 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

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6193673166

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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

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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

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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Not applicable

Data Dictionary

Not applicable