Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative Efficacy of Ivabradine Versus Beta Blockers in Treatment of Uncontrolled Permanent Atrial Fibrillation

Protocol summary

Study aim
The aim of the study is to compare the efficacy of ivabradine versus beta blockers in achieving heart rate control in patients with uncontrolled permanent atrial fibrillation and to assess their impact on various clinical parameters and safety outcomes over a specified duration.

Design
Randomized Control Trial

Settings and conduct
Study setting and conduct will be carried out at Pervaiz Ilahi Institute of Cardiology, Bahawalpur. Study will be single blinded as participants will not know which drug being given to them.

Participants/Inclusion and exclusion criteria
Inclusion Criteria; It includes adults more than 18 years of age, fulfilling the criteria of permanent atrial fibrillation, resting heart rate more than 110/min, capable of providing informed consent and previous history of pulmonary vein ablation. Exclusion Criteria; It includes individuals allergic to drugs, decompensated heart failure, Patients of hypertrophic obstructive cardiomyopathy(HOCM), acute pericarditis or myocarditis or myocardial infarction, having conditions like end stage renal disease(ESRD) or liver failure, fever, hyperthyroidism, anemia, pregnant or lactating females, severe comorbidities or history of major surgery.

Intervention groups
Two intervention group will be assigned. First group will be ivabradine group containing 30 participants. Other will be Beta blocker group of 30 participants.

Main outcome variables
Main outcome variable is heart rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241212064032N1**
Registration date: **2025-01-08, 1403/10/19**
Registration timing: **prospective**

Last update: **2025-01-08, 1403/10/19**
Update count: **0**

Registration date
2025-01-08, 1403/10/19

Registrant information

Name
Humna Chaudri

Name of organization / entity
Quaid e Azam Medical College, Bahawalpur

Country
Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-01, 1403/11/13

Expected recruitment end date
2026-01-30, 1404/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative Efficacy of Ivabradine Versus Beta Blockers in Treatment of Uncontrolled Permanent Atrial Fibrillation

Public title

Comparison of Effectiveness between Ivabradine and Beta Blockers in Patients of Permanent Atrial Fibrillation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients with ages greater than 18 years. Fulfilling the criteria of permanent atrial fibrillation. Resting heart rate (HR) greater than 110 beats per minute on ECG. Capable of willingly providing informed consent. No previous history of receiving pulmonary vein ablation.

Exclusion criteria:

Individuals who have a known allergy to drugs. Conditions such as decompensated heart failure and needing inotropic drugs or intravenous diuretics within one week before enrollment in study, being in (New York Heart Association) NYHA functional class IV, or being on the waiting list for a heart transplant. Hypertrophic obstructive cardiomyopathy, acute pericarditis, constrictive pericarditis, acute myocarditis. Patients with renal failure needing hemodialysis or with liver failure. Cardiovascular or other major surgery within one month before randomization. A severe comorbidity with a life expectancy of less than one year. Stroke, unstable angina, or acute myocardial infarction (within the last four weeks). Pregnant or breastfeeding females. Medical factors that might account for inadequate heart rate regulation including conditions such as pheochromocytoma, fever, hyperthyroidism and anemia. Inability to attend the planned appointments outlined in the procedure.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Non probability purposive sampling technique will be employed and adaptive randomization will be done according to the set criteria.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are blinded in this study as they won't know which drug group they are assigned.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Review Committee of Quaid-e-Azam Medical College,Bahawalpur

Street address

Quaid-e-Azam Medical College, Circular road, Bahawalpur

City

Bahawalpur

Postal code

63100

Approval date

2024-04-19, 1403/01/31

Ethics committee reference number

ERC/10438/PG/QMC

Health conditions studied

1

Description of health condition studied

Chronic (permanent) Atrial Fibrillation

ICD-10 code

I48.2

ICD-10 code description

Chronic atrial fibrillation

Primary outcomes

1

Description

Heart Rate control

Timepoint

Before intervention then 2 weeks and 4 weeks after intervention.

Method of measurement

Electrocardiography (ECG). Heart rate will be measured by R wave method on a rhythm strip of 10 seconds (no. of R waves in 10 seconds*6)

Secondary outcomes

1

Description

Blood Pressure

Timepoint

Before intervention, then 2 weeks and 4 weeks after intervention.

Method of measurement

BP will be measured using sphygmomanometer

2

Description
Bradycardia/Tachycardia
Timepoint
2 weeks and 4 weeks after intervention
Method of measurement
ECG and history

3

Description
Syncope
Timepoint
2 weeks and 4 weeks after intervention
Method of measurement
History

4

Description
Adverse Cardiovascular events
Timepoint
2 weeks and 4 weeks after intervention.
Method of measurement
History and medical record.

5

Description
Treatment discontinuation
Timepoint
2 weeks and 4 weeks after intervention
Method of measurement
History

Intervention groups

1

Description
Intervention Group 1; This group will consist of 30 patients of permanent uncontrolled atrial fibrillation, fulfilling inclusion criteria and intolerant to beta blockers (patients having asthma, COPD, hypotension, peripheral arterial diseases, diabetics who are prone to hypoglycemia or allergic to beta blockers). After informed consent, prospectively designed data collection Performa will be used to collect baseline information including history and demographic details. All patients will be subjected to ECG, and comprehensive clinical evaluation will be done including all baseline investigations i.e hemoglobin, serum creatinine, eGFR, transthoracic echo TTE. Systolic and diastolic BP readings and resting heart rate will be noted by duty doctor. This group will then be commenced on per oral drug IVABRADINE. A dosage of 5 milligrams per oral every 12 hours will be given for one month. Subsequently if patient tolerates this dose it can be increased to maintenance dose of 7.5 milligrams every 12 hours. Patients who are 75 years old or more will be started on 2.5 mg 12 hourly and if tolerated well the dose can increased up to 5mg 12 hourly. Two follow up visits will be planned, one after 2 weeks and second after one month since the commencement of intervention (treatment). At each visit resting heart rate (15 minutes after sitting comfortably), systolic and diastolic BP will be noted. History regarding syncope, palpitations, allergic reaction, treatment discontinuation or any adverse event will be noted on data collection Performa.
Category
Treatment - Drugs

2

Description
Intervention Group 2; This group also consists of 30 patients with uncontrolled permanent atrial fibrillation. Patients will be assigned this group after excluding any contraindication to beta blockers. After informed consent, history and basic demographic details will be noted on data collection Performa. Baseline resting heart rate ,systolic and diastolic BP will be noted. All baseline investigations will be done including ECG, hemoglobin, serum creatinine, Transthoracic echo TTE and eGFR. This group will be commenced on TABLET METOPROLOL 25 milligrams per oral 12 hourly. Subsequently the dose can be increased to therapeutic range of 25-100mg/12 hours depending upon the patient's response in following visits. Just like intervention group 1, two more follow up visits will be planned and at each visit resting heart rate, blood pressure and history regarding secondary endpoints will be noted on data collection Performa.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pervaiz Elahi Institute of Cardiology, Bahawal Victoria Hospital, Bahwalpur
Full name of responsible person
Professor Doctor Shahadat Hussain Chaudhary
Street address
Quaid-e-Azam Medical College, Circular road, Bahawalpur
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pervaiz Ilahi Institute of Cardiology, QAMC, BVH,

Bahawalpur

Full name of responsible person
Professor Doctor Shahadat Hussain Chaudhary

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Email
drshahadat@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Pervaiz Ilahi Institute of Cardiology, QAMC, BVH, Bahawalpur

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
Pervaiz Ilahi Institute of Cardiology, QAMC, BVH, Bahawalpur

Full name of responsible person
Doctor Humna Chaudri

Position
Post Graduate Resident

Latest degree
Bachelor

Other areas of specialty/work
Cardiology

Street address
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Person responsible for scientific inquiries

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Name of organization / entity
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Position
Post Graduate Resident

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Person responsible for updating data

Contact

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Position
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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

This topic is not yet discussed with the supervisor. I plan to share my data after research work is successful.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Comparative efficacy of Ivabradine and beta blockers in treatment of uncontrolled Permanent atrial fibrillation

When the data will become available and for how long

Data will be available after 6 months of publication and duration of availability will be unlimited.

To whom data/document is available

Data will only be available to the persons involved in research from institute.

Under which criteria data/document could be used

IPD data will only be shared to the persons involved in research.

From where data/document is obtainable

To the focal person responsible for research and scientific enquiries through email.

What processes are involved for a request to access data/document

One should contact the focal person through emails provided or phone number and data may take one two weeks time to process.

Comments