Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the efficacy of Ranolazine with placebo for reducing ventricular premature beats (VPBs) in patients with high burden of VPBs in holter monitoring

Protocol summary

Study aim
Comparison of the efficacy of ranolazine with placebo for reducing ventricular premature beats (VPBs) in patients with high burden of VPBs

Design
Randomized placebo-controlled trial, double blinded, two arm parallel 1:1 groups; with 96 participants; Random sequence wil be generated by R software, blockrand package

Settings and conduct
Using block randomization, patients will be allocated to two arms (1:1 ratio), receiving ranolazine or placebo. After 30 days, second visit will be done and patients will be assessed with Holter monitoring. Blinding will be achieved through using ranolazine and placebo pills that are identical in appearance, and are manufactured by the same pharmaceutical company. Participants, the principal investigator, the echocardiography specialist, the recruiting physician, the outcome assessor, and nurse investigators who collect data and complete forms will all be blinded in the trial.

Participants/Inclusion and exclusion criteria
Inclusion: Age of 18 years or older; with a premature ventricular beat burden between 10-30%. Exclusion: Ventricular tachycardia or fibrillation; atrial fibrillation; long QT interval; history of renal or hepatic disease; concurrent use of medications known to have drug interactions with ranolazine; prior recent use of ranolazine; history of adverse effects with ranolazine; pregnancy or breast feeding; not having informed consent

Intervention groups
Intervention: ranolazine 1000 mg Bid for 30 days; manufactured by Koushan Pharmed Control: placebo for 30 days; manufactured by Koushan Pharmed

Main outcome variables
Difference in ventricular premature beat burden before and after treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220515054863N2**
Registration date: **2022-11-01, 1401/08/10**
Registration timing: **prospective**

Last update: **2022-11-01, 1401/08/10**
Update count: **0**

Registration date
2022-11-01, 1401/08/10

Registrant information

Name
Masih Tajdini

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-01, 1401/09/10

Expected recruitment end date
2023-09-01, 1402/06/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of Ranolazine with placebo for reducing ventricular premature beats (VPBs) in patients with high burden of VPBs in holter monitoring

Public title
Efficacy of Ranolazine in treating ventricular premature beats

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Minimum age of 18 PVC burden between 10 to 30 percent among whole beats

Exclusion criteria:
Patients with Atrial Fibrillation (AF) Patients diagnosed with ischemic ventricular tachycardia (VT) Patients with a history of serious ventricular tachyarrhythmias in the past 4 weeks (e.g., sustained ventricular tachycardia and ventricular fibrillation) Patients who have a QT interval higher than 550 milliseconds or consume medications that prolong the QT interval Patients with a heart transplant Patients undergoing dialysis Patients with a creatinine clearance below 30 ml/min or a blood creatinine over 2.5 mg/dl Patients with moderate to severe hepatic dysfunction Patients receiving metformin with a dose extending 1000 mg Bid Patients receiving simvastatin with a daily dose extending 20 mg Patients receiving Dabigatran Patients receiving a CYP3A4 inhibitor (Ketoconazole, Clarithromycin, Ritonavir, Diltiazem, Fluconazole, Erythromycin, Verapamil or grapefruit juice) Patients with a history of Ranolazine consumption in the past two months Patients who have previously discontinued Ranolazine due to side effects Pregnant or breastfeeding patients, or patients planning for pregnancy during the study period Patients without informed consent

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants will be randomized to two 1:1 parallel arms receiving ranolazine or placebo. The random sequence will be generated by R software "blockrand" package, with the method of block randomization in block sizes of 2, 4, and 6. Trial medications (ranolazine and placebo) will be identical in appearance, and stored in sequentially numbered sealed opaque unlabeled boxing. An unblinded investigator will put a number on the medications' boxing prior to the start of recruitment, according to the random sequence. Each patient who is enrolled will receive the appropriate sequentially numbered and blinded box of medications, which contains pills prescribed for the duration of the study. Patients will receive medications after enrollment, completion of baseline forms, and providing informed consent. A randomization log will be kept at the recruitment site to ensure sequential allocation of treatments. Allocation concealment is ensured by using variable block sizes. Moreover, the ranolazine and placebo pills and their boxing are completely identical; therefore, guessing the next treatment allocation would not be possible.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding will be achieved through using ranolazine and placebo pills that are identical in appearance, and are manufactured by the same pharmaceutical company (Koushan Pharmed). Participants, the principal investigator, the echocardiography specialist, the recruiting physician, the outcome assessor, and nurse investigators who collect data and complete forms will all be blinded in the trial. Each participant receives a unique code and all of the forms will be filled out based on the code. During the statistical analysis, it will be determined whether each code is related to Ranolazine or placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran Heart Center-Tehran University of Medical Sciences

Street address
Tehran Heart Center, Kargar st

City
Tehran

Province
Tehran

Postal code
14117 13138

Approval date
2022-10-31, 1401/08/09

Ethics committee reference number
IR.TUMS.THC.REC.1401.031

Health conditions studied

1

Description of health condition studied
premature ventricular beats, ventricular premature depolarization, premature ventricular complexes, premature ventricular contraction
ICD-10 code
I49.3
ICD-10 code description
Ventricular premature depolarization

Primary outcomes

1

Description
Difference in PVC burden on holter before and after treatment
Timepoint
30 days
Method of measurement
Holter monitoring at the time of enrollment and 30 days after receiving therapy

Secondary outcomes

1

Description
Any patient-reported side effects
Timepoint
30 days
Method of measurement
interview

Intervention groups

1

Description
Intervention group: Drug name: Ranolazine, formula: C24H33N3O4, dose: 1000 mg Bid for 30 days, company: Koushan Pharmed
Category
Treatment - Drugs

2

Description
Control group: placebo, company: Koushan Pharmed
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran heart center hospital
Full name of responsible person
Ali Bozorgi
Street address
next to Jalal-e-Al-e-Ahmad Hwy, north Kargar street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
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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 University of Medical Sciences
Proportion provided by this source
38
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

2

Sponsor
Name of organization / entity
Koushan Pharmed
Full name of responsible person
Kian Saee
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No. 15, Padidar Alley, Africa Boulevard, Tehran
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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
Koushan Pharmed
Proportion provided by this source
62
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Position
Associate professor
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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

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