Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of ivabradine versus metoprolol on reducing heart rate in coronary CT-angiography candidates: A double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of ivabradine versus metoprolol on reducing heart rate in coronary CT-angiography candidates

Design
This is a Phase III double-blind randomized clinical trial with a control group with parallel groups, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct
This study will be conducted at the Farshchian Heart Hospital in Hamadan city, involving 92 eligible patients who are candidates for coronary CT-angiography. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 80 years Coronary CT angiography candidate Heart rate higher than 70 beats per minute one hour before starting CT angiography Exclusion criteria: Systolic blood pressure lower than 100 mm Hg History of coronary bypass surgery Chronic obstructive pulmonary disease

Intervention groups
Intervention group 1: Ivabradine tablets 7.5 mg one dose. If the heart rate does not decrease after one hour, the dose will be repeated. Intervention group 2: Metoprolol 50 mg tablet, one dose. If the heart rate does not decrease after one hour, the dose will be repeated.

Main outcome variables
Primary outcome: Heart rate, systolic and diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N522**
Registration date: **2024-08-24, 1403/06/03**
Registration timing: **prospective**

Last update: **2024-09-19, 1403/06/29**
Update count: **1**

Registration date
2024-08-24, 1403/06/03

Registrant information

Name
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Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-22, 1403/07/01

Expected recruitment end date
2024-12-21, 1403/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of ivabradine versus metoprolol on reducing heart rate in coronary CT-angiography candidates: A double-blind randomized clinical trial

Public title
The effect of ivabradine versus metoprolol on reducing heart rate in coronary CT-angiography candidates

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 80 years Coronary CT angiography candidate Heart rate higher than 70 beats per minute one hour before starting CT angiography

Exclusion criteria:
Systolic blood pressure lower than 100 mm Hg History of coronary bypass surgery Chronic obstructive pulmonary disease

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. Therefore, the trial will be conducted as a double-blind study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave

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Province
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Postal code
6517838695

Approval date
2024-08-10, 1403/05/20

Ethics committee reference number
IR.UMSHA.REC.1403.297

Health conditions studied

1

Description of health condition studied
Coronary artery disease

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Heart rate

Timepoint
Every 15 minutes until CT angiography

Method of measurement
With the monitor

2

Description
Systolic and diastolic blood pressure

Timepoint
Every 15 minutes until CT angiography

Method of measurement
With the monitor

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Ivabradine tablets 7.5 mg one dose. If the heart rate does not decrease after one hour, the dose will be repeated.
Category
Treatment - Drugs

2

Description
Intervention group 2:Metoprolol 50 mg tablet, one dose. If the heart rate does not decrease after one hour, the dose will be repeated.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Heart Hospital in Hamadan city
Full name of responsible person
Mohammad Fazel Mousavi
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Sponsors / Funding sources

1

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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
Hamedan 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
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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
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