

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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

City

Hamadan

Province

Hamadan

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

Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 1740

Email

Mousavimohamd12@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

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

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad Fazel Mousavi

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

School of Medicine, Hamadan University of Medical Sciences, Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

Mousavimohamd12@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Seyed Kianoosh Hoseini

Position

Cardiologist

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

School of Medicine, Hamadan University of Medical Sciences, Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

k.hoseini86@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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