

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 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

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##### 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

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##### Province

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##### 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.

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##### 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

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**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

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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