

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of bisoprolol monotherapy for the management of hypertension of otherwise healthy adults younger than 60 years compared to the standard therapy with valsartanamlodipine

Protocol summary

Study aim

Determination of the exact amount of blood pressure changes in patients by bisoprolol and valsartan - amlodipine Determining the effect of different individual characteristics (such as age, sex, other diseases, etc.) on achieving the goals of controlling blood pressure by each of bisoprolol and valsartan - amlodipine drugs Comparison of Patient Tolerance and Acceptance between Bisoprolol and Valsartan Amlodipine

Design

After eligibility is assessed, patients are randomly selected using block randomization with block size 4. All participants will be informed about the objectives of the study and will be asked for their informed written consent.

Settings and conduct

professor Kojuri Cardiology Clinic To achieve blinding, patients are randomly divided into groups A and B. Group A will be allocated to bisoprolol and Group B to valsartan + amlodipine, but this allocation will not be evident to the project implementers and study analysts until the end of the study.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study will be age between 18 and 60 years and stage one or two hypertension (both stages, but no more than 180/110, and recently diagnosed). exclusion criteria, any contraindications to beta-blockers, CCBs, or ARBs (e.g., symptomatic bradycardia, asthma, advanced renal failure, serum potassium > 5.5 mEq/L, severe lower extremity edema, etc.), associated complications that suggest the use of a specific agent (e.g., diabetes, heart failure, CKD, etc.), extremely high blood pressure (SBP>=180 and/or DBP>=110), and use of other medications associated with beta-blockers, CCBs or ARBs interfere with, will be.

Intervention groups

به والسارتان + آملودیپین اختصاص B به بیزوپرولول و گروه A روه

داده می شود

Main outcome variables

To determine how effective bisoprolol monotherapy may be in controlling blood pressure in young and middle-aged adults.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240701062299N2**

Registration date: **2025-01-28, 1403/11/09**

Registration timing: **retrospective**

Last update: **2025-01-28, 1403/11/09**

Update count: **0**

Registration date

2025-01-28, 1403/11/09

Registrant information

Name

Seyed Alireza Mirhosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 0508

Email address

mirhosseini.alireza.1999@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-01, 1401/05/10

Expected recruitment end date

2022-12-31, 1401/10/10

Actual recruitment start date

2022-08-01, 1401/05/10

Actual recruitment end date

2022-12-31, 1401/10/10

Trial completion date

empty

Scientific title

The effect of bisoprolol monotherapy for the management of hypertension of otherwise healthy adults younger than 60 years compared to the standard therapy with valsartanamlodipine

Public title

Bisoprolol vs, standard therapy; managing Hypertension in adults

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age between 18 and 60 years stage one or two hypertension recently diagnosed

Exclusion criteria:

any contraindications to beta-blockers, CCBs, or ARBs (e.g. symptomatic bradycardia, asthma, advanced renal failure, serum potassium > 5.5 mEq/L, severe edema of the lower extremities, etc.), associated complications that suggest the use of a specific agent (e.g., diabetes, heart failure, CKD, etc.), They will have extremely high blood pressure (SBP>= 180 and/or DBP>= 110), and the use of other medications that interact with beta-blockers, CCBs, or ARBs.

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Actual sample size reached: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

After checking eligibility, patients are randomly selected using block randomization method with a block size of 4. To achieve blinding, patients are randomly divided into groups A and B. Group A is assigned to bisoprolol and group B is assigned to valsartan + amlodipine.

Blinding (investigator's opinion)

Triple blinded

Blinding description

To achieve blinding, patients are randomly divided into groups A and B. Group A will be allocated to bisoprolol and Group B to valsartan + amlodipine, but this allocation will not be evident to the project implementers

and study analysts until the end of the study.

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

Above Qasr-e-Dasht Square, East Mirza Shirazi Street, Alley 7 Side of Haft Momayez Eight, the second alley on the right

City

shiraz

Province

Fars

Postal code

7187873641

Approval date

2023-07-23, 1402/05/01

Ethics committee reference number

IR.SUMS.MED.REC.1402.206

Health conditions studied**1****Description of health condition studied**

Hypertension

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Blood pressure control

Timepoint

Q: From the start of the study, patients will be followed up on a weekly basis with phone calls (by experienced medical staff with sufficient knowledge about hypertension and its complications) to assess their blood pressure levels (and assess the need to adjust the dose, or change in medications to prevent any disease) and after 2 months, secondary ABPM will be performed for all participants to help us in the analysis. and help analyze the data accurately and discuss the results.

Method of measurement

Q: From the start of the study, patients will be followed up on a weekly basis with phone calls (by experienced

medical staff with sufficient knowledge about hypertension and its complications) to assess their blood pressure levels (and assess the need to adjust the dose, or change in medications to prevent any disease) and after 2 months, secondary ABPM will be performed for all participants to help us in the analysis. and help analyze the data accurately and discuss the results.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: bisoprolol monotherapy

Category

Treatment - Drugs

2

Description

Control group: valsartan-amlodipine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Proffesor Kojuri Cardiology Clinic

Full name of responsible person

Javad kojuri

Street address

Shiraz - Shahid Chamran Boulevard - Niayesh
Boulevard - Niayesh Subspecialty Complex

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

-

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Javad Kojuri

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only a part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of the Access Period 6 months after the results are printed

To whom data/document is available

It will be available for researchers working in academic and scientific institutions

Under which criteria data/document could be used

-

From where data/document is obtainable

Info@kojuriclinic.com

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

Start of the Access Period 6 months after the results are printed

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

Shiraz University of Medical Sciences

Full name of responsible person

Javad Kojuri

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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