Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

روه A به بیزوپرولول و گروه B به والسارتان + آملودیپین اختصاص داده می شود،

Main outcome variables

To determine how effective bisprolol 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
City
Shiraz
Province
Fars
Postal code
-
Phone
+98 71 3654 0082
Email
Info@kojuriclinic.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
-
Street address
-
City
shiraz
Province
Fars
Postal code
-
Phone
+98 71 3230 5410
Email
Info@kojuriclinic.com
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
Street address
Cardiology department, Alzahra Heart Hospital, Sibooye Blvd
City
Shiraz
Province
Fars
Postal code
-
Phone
+98 71 3735 5093
Email
kojurij@yahoo.com

Person responsible for scientific 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
Street address
Cardiology department, Alzahra Heart Hospital, Sibooye Blvd
City
Shiraz
Province
Fars
Postal code
-
Phone
+98 71 3735 5093
Email
kojurij@yahoo.com

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
Street address
Cardiology department, Alzahra Heart Hospital, Sibooye Blvd
City
Shiraz
Province
Fars
Postal code
-
Phone
+98 71 3735 5093
Email
kojurij@yahoo.com

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