Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of Valsartan 80mg and Amlodipine 5mg as combination fix dose therapy and combination free drug therapy in controlling 24-hour ambulatory blood pressure

Protocol summary

Study aim

Comparison between the effect of Valsartan 8· mg and Amlodipine 5 mg as combination fix dose therapy and combination free drug therapy in controlling 24-hour ambulatory blood pressure

Design

Randomized, double blind clinical trial, with two parallel groups, phase 3 on 136 patients.

Settings and conduct

This study will be performed in Professor Kojuri heart clinic in Shiraz. One of the intervention groups will receive Valsartan 80mg and Amlodipine 5mg as combination fix dose in a single pill daily and another group will receive the same drugs as combination free drug in multi pills daily.Both groups undergo 24-hour ambulatory blood pressure monitoring with holter before starting treatment and 2 months after receiving medications. Patients, physicians, staff and those who analyze the results won't be aware of the patient grouping. To achieve blinding, patients will be divided into groups A and B with the mentioned randomization method but this allocation won't be evident to those mentioned earlier.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- age between 35-70 2- new case of hypertension 3- stage 1, 2 hypertension Exclusion criteria: 1- severe hypertension 2- secondary hypertension 3- patients with positive history of ischemic heart disease 4- patients who received anti-hypertensive drugs before study 5- patients who are not volunteered

Intervention groups

One of the intervention groups will receive Valsartan 80 mg and Amlodipine 5mg as combination fix dose in a single pill daily and another group will receive Valsartan 80 mg and Amlodipine 5mg as combination free drug in multi pills daily. Both groups undergo 24-hour ambulatory blood pressure monitoring with holter before starting treatment and 2 months after receiving medications.

Main outcome variables

Average 24-hour, daytime and nighttime systolic and diastolic blood pressure,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221016056199N1**
Registration date: **2022-12-11, 1401/09/20**
Registration timing: **prospective**

Last update: **2022-12-11, 1401/09/20**
Update count: **0**

Registration date

2022-12-11, 1401/09/20

Registrant information

Name

Kimia Falamarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3646 3245

Email address

kimiafalamarzi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of Valsartan 80mg and Amlodipine 5mg as combination fix dose therapy and combination free drug therapy in controlling 24-hour ambulatory blood pressure

Public title
The effect of Valsartan and Amlodipine combination with two different forms in controlling 24-hour ambulatory blood presure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
New case of hypertension stage 1 or 2 hypertension
Exclusion criteria:
Severe hypertension Secondary hypertension Positive history of ischemic heart disease Patients on anti-hypertensive drugs beforehand Patients who are not volunteered
Age
From **35 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **136**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization in this study was performed using permutation block randomization method (with block size=4). Patients will be assigned to each groups according to random list obtained by computer and randomization.com site. An assistant will include eligible patients to each groups (group A and B) according to random list and will divide Patients randomly into two groups of 68 using random list. The assistant is a different person from researchers and physicians involved in this study. Researchers and physicians are not aware of patients grouping and this allocation will not be evident to the conductors and study analyzers until the end of the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
Physicians, staff and those who analyze and evaluate the study results will not be aware of the patient grouping. To achieve blinding, patients will be divided into groups A and B with the mentioned randomization method but this allocation will not be evident to the conductors and study analyzers until the end of the study. Moreover, those who will collect holter data and those who will analyze and evaluate the data will not be aware of the patients grouping.
Placebo
Not used
Assignment
Parallel
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
Shiraz university of medical sciences, school of medicine, Emam Hossein Square, Zand Blvd
City
Shiraz
Province
Fars
Postal code
7134845794
Approval date
2021-12-21, 1400/09/30
Ethics committee reference number
IR.SUMS.MED.REC.1400.505

Health conditions studied

1

Description of health condition studied
Essential Hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Average 24-hour systolic and diastolic blood pressure
Timepoint
At the beginning of the study and 60 days after starting treatment
Method of measurement
Holter monitoring of blood pressure

2

Description
mean arterial pressure
Timepoint
At the beginning of the study and 60 days after starting treatment
Method of measurement
Holter monitoring of blood pressure

Secondary outcomes

1

Description
Average daytime systolic and diastolic blood pressure
Timepoint
At the beginning of the study and 60 days after starting treatment
Method of measurement
Holter monitoring of blood pressure

2

Description
Average nighttime systolic and diastolic blood pressure
Timepoint
At the beginning of the study and 60 days after starting treatment
Method of measurement
Holter monitoring of blood pressure

Intervention groups

1

Description
Intervention group 1: In this group, 68 patients randomly undergo 24-hour ambulatory blood pressure monitoring with blood pressure holter and then combination fix dose of Valsartan 80mg and amlodipine 5mg (single pill) (Valzomix from Abidi pharmaceutical company) will be used per oral daily for 2 months and after that patients undergo another 24-hour ambulatory blood pressure monitoring with blood pressure holter. The patients who were not known cases of hypertension and their high blood pressure were diagnosed in routine check ups will enter the study according to inclusion and exclusion criteria. Their 24-hour blood pressure will be measured by blood pressure holter and then fix dose combination of Valsartan 80mg and amlodipine 5mg once daily will be started for them. 72 hours later and also a month later patients will be asked and monitored whether any side effects has happened and whether they are consuming medication in a right way. After 2 months patients' 24-hour blood pressure will be measured again by blood pressure holter.
Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, 68 patients randomly undergo 24-hour ambulatory blood pressure monitoring with blood pressure holter and then free drug combinations of Valsartan 80mg (Valsacor from Actoverco company) and amlodipine 5mg (Amlober from Actoverco company) (multi pill) will be used per oral daily for 2 months and after that patients undergo another 24-hour ambulatory blood pressure monitoring with blood pressure holter. The patients who were not known cases of hypertension and their high blood pressure were diagnosed in routine check ups will enter the study according to inclusion and exclusion criteria. Their 24-hour blood presuure will be measured by blood pressure holter and then free drug combination of Valsartan 80mg and amlodipine 5mg once daily will be started for them. 72 hours later and also a month later patients will be asked and monitored whether any side effects has happened and whether they are consuming medication in a right way. After 2 months patients' 24-hour blood pressure will be measured again by blood pressure holter.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Professor Kojuri heart clinic
Full name of responsible person
Javad Kojuri
Street address
Niayesh complex, Niayesh Blvd, Chamran Blvd
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-
Phone
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Email
Info@kojuriclinic.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Memarpour
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7th floor, Shiraz University of Medical Sciences central building, Zand Blvd

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-
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+98 71 3235 7282
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vcrdep@sums.ac.ir
Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Professor Kojuri heart clinic

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Kimia Falamarzi
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Person responsible for updating data

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Latest degree
A Level or less
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Due to confidentiality of patients' information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report

No - There is not 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