Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparison of the effect of single-pill combination of valsartan / amlodipine with valsartan alone on left ventricular diastolic dysfunction(LVDD) in patients with hypertension(HTN)

Protocol summary

Study aim

Comparison of the effect of single-drug combination of valsartan / amlodipine with valsartan alone on left ventricular diastolic dysfunction in patients with hypertension

Design

In this double_blind clinical trial, 122 patients with hypertension and left ventricular diastolic dysfunction were randomly divided into two groups using sas software.In Phase 2, 61 patient in one group will receive single pill Valsartan/ Amlodipine 80/5 and in the other group 61 patient will receive Valsartan 80 alone.

Settings and conduct

Outpatients referred to the Clinic of Bou Ali Sina Hospital in Qazvin between 1399-1400, patients who suffered from high blood pressure, randomly devided to two Groups.we tried in first group a single-Pill Valsartan/Amlodipine 80/5 and Valsartan 80 for the second group.Once at the end of the first month,If the blood pressure is not reached to the target,our approach will be increasing the dose of the single pill Valsartan/Amlodipine to160/5 in the first group and using valsartan twice daily in second group.Finally, if the blood pressure is not controlled, that patient excluded from this study and treated with other classes of drugs.Then second echocardiography is performed sixth months later and evaluate left ventricular diastolic function.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- HTN (Grade 1 and more) 2- detectingLVDD on echocardiography Exclusion criteria: 1-Taking ARB or ACEI drugs in the last three months 2 - left ventricular ejection fraction(LVEF) less than50% 3- Previous allergy or contraindication to the use of the studied drugs 4 Serum Cr above 1.5 5- Lack of blood pressure control 6 -Patient dissatisfaction with continuing the study 7 -Severe valvular disease on echo

Intervention groups

A group receiving single-pill Valsartan /Amlodipine A group receiving Valsartan alone

Main outcome variables

Left ventricular diastolic dysfunction

General information

Reason for update

Acronym

LVDD

IRCT registration information

IRCT registration number: **IRCT20201102049232N1**
Registration date: **2021-01-01, 1399/10/12**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-01, 1399/10/12**
Update count: **0**

Registration date

2021-01-01, 1399/10/12

Registrant information

Name

Ali Pazoki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3332 6034

Email address

a.pazoki@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-06-22, 1400/04/01

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

Scientific title
Comparison of the effect of single-pill combination of valsartan / amlodipine with valsartan alone on left ventricular diastolic dysfunction(LVDD) in patients with hypertension(HTN)

Public title
effect of valsartan / amlodipine on LVDD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with newly diagnosed hypertension Patients with hypertension with evidence of echocardiographic LVDD
Exclusion criteria:
Taking ARB or ACEI drugs in the last three months Left Ventricular Ejection Fraction less than 50% Major valvular heart disease Previous allergy or contraindication to the use of the studied drugs Serum creatinine above 1.5 Lack of blood pressure control with the studied drugs Patient dissatisfaction with continuing the study
Age
To **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **122**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Randomization sas Random allocation software
Blinding (investigator's opinion)
Double blinded
Blinding description
The attending physician in the clinic, after examining and examining the entry criteria and after randomization, refers the patient along with the form sheet and completing the initial information for monitoring and delivery of the drug. After delivery of the drug, the patient is referred to the echo unit for echo and monitoring. From now on, the monitors and people who do the echo at the beginning of the visit and 6 months later and the project analyzer do not know about the patient's medication.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Bou Ali Street, Bou Ali Sina Hospital
City
qazvin
Province
Qazvin
Postal code
3413786165
Approval date
2020-08-19, 1399/05/29
Ethics committee reference number
IR.QUMS.REC.1399.179

Health conditions studied

1

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

2

Description of health condition studied
Left ventricular diastolic dysfunction
ICD-10 code
I50.3
ICD-10 code description
Diastolic (congestive) heart failure

Primary outcomes

1

Description
Left ventricular diastolic dysfunction
Timepoint
At the beginning of the study and 6 months after starting medication for hypertension
Method of measurement
Trans thoracic echocardiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: There is a group that receive Abaidi's single pill Valsartan / Amlodipine 80/5 for one month and if the blood pressure is not controlled, the dose will increase to160/5.
Category
Treatment - Drugs

2

Description
Intervention group:There is a group that receives Valsartan80 mg daily of Abaidi alone for a month, and if blood pressure is not controlled, the dose will increase to 160 mg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bou Ali Sina Hospital
Full name of responsible person
Zohreh Toudehrousta
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Mohammad Mehdi Emamjumeh
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Qazvin University of Medical Sciences ,Shahid Bahonar Blvd ,Qazvin,
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Dr. Abidi Pharmaceutical Company
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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Ali Pazoki
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after unidentified individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Academic and scientific researchers and Industries
Under which criteria data/document could be used
Permission is granted to use the data for meta-analysis or to design other studies
From where data/document is obtainable
Submit request via email dralipazoki@gmail.com a.pazoki@qums.ac.ir
What processes are involved for a request to access data/document
If the applicant submits a request, if 6 months have passed since the publication of the article, it will be answered in less than 1 week.
Comments