

# 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 divided 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 to 160/5 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 six months later and evaluate left ventricular diastolic function.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- HTN ( Grade 1 and more) 2- detecting LVDD on echocardiography Exclusion criteria: 1-Taking ARB or ACEI drugs in the last three months 2 - left ventricular ejection fraction(LVEF) less than 50% 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

Bou Ali Street -Qazvin

#### City

Qazvin

#### Province

Qazvin

#### Postal code

3413786165

#### Phone

+98 28 3332 6033

#### Email

dralipazoki@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Qazvin University of Medical Sciences

#### Full name of responsible person

Dr. Mohammad Mehdi Emamjume

#### Street address

Qazvin University of Medical Sciences ,Shahid Bahonar Blvd ,Qazvin,

#### City

Qazvin

### Province

Qazvin

### Postal code

3419915315

### Phone

+98 28 3337 5152

### Email

info@qums.ac.ir

### 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

Cardiology

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Bouali Street, Bouali Hospital, Secretariat

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## Person responsible for scientific 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**

Cardiology

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**Email**

zohretuderusta@gmail.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**

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

Qazvin University of Medical Sciences

**Full name of responsible person**

zohre Toudehrousta

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Cardiology

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