

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Sacubitril-Valsartan versus angiotensin-converting enzyme inhibitors (ACEI) and angiotensin receptor blocker (ARB) on left ventricular ejection fraction in patient with heart failure: a double-blind randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of Sacubitril-Valsartan versus angiotensin-converting enzyme inhibitors (ACEI) and angiotensin receptor blocker (ARB) on left ventricular ejection fraction in patient with heart failure

##### Design

This is a Phase III double-blind randomized clinical trial with a control group with parallel groups, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

##### Settings and conduct

This study will be conducted at the Farshchian Heart Hospital in Hamadan city, involving 225 eligible patients with heart failure. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 80 years Heart failure  
Exclusion criteria: Severe coronary disease Valvular heart disease Pulmonary thromboembolism Congenital heart disease

##### Intervention groups

Intervention group 1: Sacubitril-valsartan tablets 24/26 mg every 12 hours for 6 months  
Intervention group 2: Angiotensin converting enzyme inhibitor (ACEI) 12/5 mg every 12 hours for 6 months  
Intervention group 3: Angiotensin receptor blocker (ARB) 12/5 mg every 12 hours for 6 months

##### Main outcome variables

Primary outcome: Average blood pressure, mean serum creatinine, the average quality of life score, left heart ejection fraction, the frequency and duration of hospitalization, the occurrence of death

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N503**

Registration date: **2024-03-13, 1402/12/23**

Registration timing: **prospective**

Last update: **2024-03-13, 1402/12/23**

Update count: **0**

##### Registration date

2024-03-13, 1402/12/23

##### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-20, 1403/02/01

##### Expected recruitment end date

2024-10-22, 1403/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Effect of Sacubitril-Valsartan versus angiotensin-converting enzyme inhibitors (ACEI) and angiotensin receptor blocker (ARB) on left ventricular ejection fraction in patient with heart failure: a double-blind randomized clinical trial

**Public title**  
Effect of Sacubitril-Valsartan versus angiotensin-converting enzyme inhibitors (ACEI) and angiotensin receptor blocker (ARB) on left ventricular ejection fraction in patient with heart failure

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age 18 to 80 years Heart failure  
**Exclusion criteria:**  
Severe coronary disease Valvular heart disease  
Pulmonary thromboembolism Congenital heart disease

**Age**  
From **18 years** old to **80 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: **225**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, random assignment of patients to the intervention and control groups will be performed using block randomization. To achieve this, six sheets of paper will be prepared - two with the name of "Intervention 1," two with the name of "Intervention 2," and two with the name of "Control." These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. Therefore, the trial will be conducted as a double-blind study.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics Committee of Hamadan University of Medical Sciences  
**Street address**  
Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Fahmideh Ave  
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Hamadan  
**Province**  
Hamadan  
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6517838695

**Approval date**  
2023-08-26, 1402/06/04

**Ethics committee reference number**  
IR.UMSHA.REC.1402.425

**Health conditions studied**

**1**

**Description of health condition studied**  
Heart failure

**ICD-10 code**  
I50

**ICD-10 code description**  
Heart failure

**Primary outcomes**

**1**

**Description**  
Average blood pressure

**Timepoint**  
Every 2 weeks for 6 months after the intervention

**Method of measurement**  
Using a sphygmomanometer

**2**

**Description**  
Mean serum creatinine

**Timepoint**  
Every 2 weeks for 6 months after the intervention

**Method of measurement**

By taking blood samples

### 3

#### **Description**

The average quality of life score

#### **Timepoint**

Every 2 weeks for 6 months after the intervention

#### **Method of measurement**

Using the New York Heart Association (NYHA) questionnaire

### 4

#### **Description**

Left heart ejection fraction

#### **Timepoint**

Every 2 weeks for 6 months after intervention

#### **Method of measurement**

With echocardiography

### 5

#### **Description**

The frequency and duration of hospitalization

#### **Timepoint**

Within 6 months after the intervention

#### **Method of measurement**

By examining the medical record

### 6

#### **Description**

The occurrence of death

#### **Timepoint**

Within 6 months after the intervention

#### **Method of measurement**

By examining the medical record

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: Sacubitril-valsartan tablets 24/26 mg every 12 hours for 6 months

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 2: Angiotensin converting enzyme inhibitor (ACEI) 12/5 mg every 12 hours for 6 months

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Intervention group 3: Angiotensin receptor blocker (ARB) 12/5 mg every 12 hours for 6 months

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Farshchian Heart Hospital in Hamadan city

##### **Full name of responsible person**

Dr. Farnoosh Masmou

##### **Street address**

Farshchian Heart Hospital, Shahid Fahmideh Ave.

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Hamedan University of Medical Sciences

##### **Full name of responsible person**

Dr. Reza Shokoohi

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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**

Hamedan 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**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Farnoosh Masmou  
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Resident of Cardiology  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available