

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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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
City
Hamadan
Province
Hamadan
Postal code
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

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Farshchian Heart Hospital, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
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Resident of Cardiology
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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