Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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

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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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Farnoosh Masmou

Position

Resident of Cardiology

Latest degree

Medical doctor

Other areas of specialty/work

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