

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of the effect of sacubitril valsartan on lv remodeling In patients with ischemic heart failure by 2D volumetry assessment

Protocol summary

Study aim

Evaluation of the effect of sacubitril valsartan on lv remodelling In patients with ischemic heart failure by 2D volumetry assessment

Design

Clinical trial without a control group, community-based and practice-oriented, parallel groups, without blinding, randomized, phase 2 on 92 patients (46 people receiving valsartan drug and 46 people receiving sacubitril valsartan drug). A simple randomization method was used for randomization.

Settings and conduct

To investigate the effect of valsartan sacubitril on LV remodelling in patients with ischemic heart failure using the 2D volumetric assessment method, patients diagnosed with coronary artery disease who are referred to Imam Khomeini Hospital and Golestan Ahvaz are randomly divided into two groups. The first group will receive valsartan and the second group will receive sacubitril valsartan. Also, the study is done without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: consent to participate in the study, heart failure patients with LVEF less than 40, coronary artery disease, history of plastic surgery, coronary artery bypass surgery. Exclusion criteria : Insulin-dependent diabetes mellitus, respiratory diseases, Chronic kidney diseases, Uncontrolled blood pressure.

Intervention groups

The first group: treatment with valsartan drug (Arena company) once a day for 6 months. The second group: treatment with sacubitril valsartan drug (Arena company) once a day for 6 months.

Main outcome variables

Left Ventricular Ejection Fraction; Cardiac index; Left ventricular end-diastolic volume; Left Ventricular End-Systolic Volume; Six Minute Walk Test.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240117060713N1**

Registration date: **2024-01-27, 1402/11/07**

Registration timing: **prospective**

Last update: **2024-01-27, 1402/11/07**

Update count: **0**

Registration date

2024-01-27, 1402/11/07

Registrant information

Name

Farzaneh Ahamdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3311 0000

Email address

ahmadi-far@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-03, 1402/11/14

Expected recruitment end date

2024-08-04, 1403/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of sacubitril valsartan on lv remodeling In patients with ischemic heart failure by 2D volumetry assessment

Public title

Investigating the effect of valsartan sacubitril on left ventricular function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the study Heart failure patients with LVEF less than 40 Coronary Artery Disease History of angioplasty Coronary artery bypass surgery

Exclusion criteria:

Insulin-dependent diabetes mellitus respiratory diseases Chronic kidney diseases Uncontrolled blood pressure

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with eligibility criteria will be divided into two groups using a randomized block design. An online website (<https://www.sealedenvelope.com>) is used to generate a random list based on the desired sample size and block size of 4. After creating a list, each patient will be identified with a unique code throughout the study. 46 people are selected for each intervention group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jundishapur Ahvaz University of Medical Sciences

Street address

Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6441945781

Approval date

2024-01-10, 1402/10/20

Ethics committee reference number

IR.AJUMS.REC.1402.539

Health conditions studied

1

Description of health condition studied

Ischemic Heart Disease

ICD-10 code

I24

ICD-10 code description

Other acute ischemic heart diseases

Primary outcomes

1

Description

Left Ventricular Ejection Fraction

Timepoint

Before and after 6 months of intervention

Method of measurement

Echocardiography

2

Description

Left ventricular end-diastolic volume

Timepoint

Before and after 6 months of intervention

Method of measurement

Echocardiography

3

Description

Left Ventricular End-Systolic Volume

Timepoint

Before and after 6 months of intervention

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

After 6 months of intervention

Method of measurement

Examination of patient records

2

Description

Mortality

Timepoint

After 6 months of intervention

Method of measurement

Examination of patient records

Intervention groups

1

Description

Intervention group: Valsartan (Arena company) treatment once a day for 6 months

Category

Treatment - Drugs

2

Description

Intervention group: Treatment with sacubitril valsartan (Arena company) once a day for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Ahvaz

Full name of responsible person

Farzaneh Ahamdi

Street address

24-meter Street

City

Ahvaz

Province

Khouzestan

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6193673166

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+98 916 111 3490

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2

Recruitment center

Name of recruitment center

Golestan Hospital, Ahvaz

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Street address

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Ahvaz

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6135715794

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+98 61 4133 0000

Email

zakerkish-m@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Farzaneh Ahamdi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable