Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 refered 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
Postal code
6193673166
Phone
+98 916 111 3490
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ahmadi-far@ajums.ac.ir

2

Recruitment center
Name of recruitment center
Golestan Hospital, Ahvaz
Full name of responsible person
Farzaneh Ahamdi
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Province
Khouzestan
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Phone
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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
Golestan
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+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

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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