Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

The Effectiveness of Sacubitril-Valsartan with ACEI/ARBs on Right Ventricular Function in Patients with Right Sided Heart Failure; A Randomized Clinical Controlled Trial

Protocol summary

Study aim
Comparison of the effectiveness of sacubitril-valsartan along with ACEI/ARB drugs on right ventricular function in patients with right heart failure

Design
Clinical trial with two arm parallel group,open label with simple randomization in phase 3 on 84 patients of right sided HF

Settings and conduct
Sampling will be done for patients with RV failure who require treatment with ARNI/ARB/ACEI admitted to Rasool Akram hospital or outpatient clinic for 3 months.in final selected groups , an echocardiography will be done by the related fellowship. treatment period will be started and patients will routinely be observed for their clinical status. another echo will be done at the end of the semestre. indexes related to RV function are going to be measured and then improvement of these indexes will be compared betweeen the groups by SPSS.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 18, right sided heart failure
Exclusion criteria: GFR<30, Cr>2.5, SBP<100

Intervention groups
Intervention group: patients with right heart failure who receive Sacubitril valsartan. control group 1: patients with right heart failure who receive Losartan. control group2: patients with right heart failure who receive Captopril.

Main outcome variables
LV ejection fraction, RV dysfunction, RV diameter in diastole, LV end systolic and diastolic diameter, diastolic function of ventricles, RV-PA coupling, Pulmonary artery systolic pressure, fractional area change, function class of the patient.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230926059524N1**
Registration date: **2023-12-28, 1402/10/07**
Registration timing: **prospective**

Last update: **2023-12-28, 1402/10/07**
Update count: **0**

Registration date
2023-12-28, 1402/10/07

Registrant information
Name
Elahe Zeinali
Name of organization / entity
Country
Iran (Islamic Republic of)
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Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-01-21, 1402/11/01
Expected recruitment end date
2024-04-20, 1403/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of Sacubitril-Valsartan with ACEI/ARBs on Right Ventricular Function in Patients with Right Sided Heart Failure; A Randomized Clinical Controlled Trial

Public title
The Effect of Sacubitril-Valsartan on RV function

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients who aged over 18 years old patients with any degree of right ventricular failure written and informed consent

Exclusion criteria:
glomerular filteration rate less than 30 mg/dl systolic blood pressure less than 100 mmHg history of angioedema right heart failure due to acute pulmonary emboli creatinine more than 2.5mg/dl renal artery stenosis hisory of intolerance to the mentioned drugs Death Lack of consent to prticipate in the study

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
In this clinical trial study, 84 patients with Right Sided Heart Failure will be included in the study. For random allocation of individuals in the study groups (intervention group and comparison group), the method of random allocation with block method (Block Randomization) will be used. In this method, blocks with a size of six (including three people in the intervention group and three people in the comparison group) with a ratio of 1:1 will be used (14 blocks of 6). Random Allocation software will be used to generate random sequences. The random allocation concealment method is used in such a way that random sequences are created. In this method, they are identified on the cards and these cards are placed inside the sealed envelopes in order. In order to maintain the created sequence, the numbering will be recorded on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder. Then, according to the order of entry of the eligible participants, the envelopes will be opened and the assigned group of the participant will be determined.

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 Iran university of medical science

Street address
Rasool akram hospital, Maziar Mansouri st, SattarKhan Ave.

City
Tehran

Province
Tehran

Postal code
1445613131

Approval date
2023-03-05, 1401/12/14

Ethics committee reference number
IR.IUMS.FMD.REC.1401.706

Health conditions studied

1

Description of health condition studied
Ischemic cardiomyopathy

ICD-10 code
I25.5

ICD-10 code description
Ischemic cardiomyopathy

2

Description of health condition studied
Dilated cardiomyopathy

ICD-10 code
I42.0

ICD-10 code description
Dilated cardiomyopathy

Primary outcomes

1

Description
degree of RV dysfunction

Timepoint
At the beginning of the trial, 3 months after using the drug

Method of measurement
Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Sacubitril valsartan (under the brand name: Artrestan, Arena Hayat co) with the starting dose of 50mg twice daily will be prescribed to patients with any degree of RV dysfunction on the condition of systolic blood pressure at more than 100mmHg, creatinine less than 2.5. on the follow up visits,the dose will be escalated to 100mg twice daily if the patient could tolerate that.at the end of the trimestre, the patients will have another echocardiography done again

Category
Treatment - Drugs

2

Description
Control group: Losartan(under the brand name: losartan, Zagros co.) with the starting dose of 25mg daily will be prescribed to patients with any degree of RV dysfunction on the condition of systolic blood pressure at more than 100mmHg, creatinine less than 2.5. on the follow up visits,the dose will be escalated to 50mg daily if the patient could tolerate that.at the end of the trimestre, the patients will have another echocardiography done again

Category
Treatment - Drugs

3

Description
Control group: Captopril (under the brand name: Tedapharm, Tehran Darou co.) with the starting dose of 6.25mg TDS will be prescribed to patients with any degree of RV dysfunction on the condition of systolic blood pressure at more than 100mmHg, creatinine less than 2.5. on the follow up visits,the dose will be escalated to 50mg TDS if the patient could tolerate that.at the end of the trimestre, the patients will have another echocardiography done again

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasool Akram hospital

Full name of responsible person
Elahe Zeinali

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Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mousavizade, Kazem

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Zeinali, Elahe

Position
Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Latest degree

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Latest degree

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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