

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 semester. Indexes related to RV function are going to be measured and then improvement of these indexes will be compared between 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 group 2: 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)

Phone

+98 34 3422 6260

Email address

elahezeinali@gmail.com

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 filtration 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 history of intolerance to the mentioned drugs Death Lack of consent to participate 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

Street address

Rasool Akram hospital, Maziar Mansouri st, Sattarkhan ave.

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2466

Email

Rasoolhospital@iums.ac.ir

Web page address

<https://hrmc.iums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mousavizade, Kazem

Street address

Iran university of medical science, Hemmat hwy

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2504

Fax

+98 21 8862 2307

Email

Research-m@iums.ac.ir

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

Street address

Rasool akram hospital, Maziar Mansouri st, Sattarkhan ave.

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2466

Email

Elahezeinali93@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Elahe Zeinali

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

2nd floor, No. 22, Fath street, 3rd Fath alley, Adl Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 34 3422 6260

Fax

Email

Elahezeinali93@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Elahe Zeinali

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

2nd floor, No. 22, Fath street, 3rd Fath alley, Adl Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 34 3422 6260

Fax

Email

Elahezeinali93@gmail.com

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