Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation the efficacy of diuretic therapy with furosemide compared with combined diuretic therapy with furosemide and indapamide in treatment of patients with congestive heart failure: A randomized clinical trial

Protocol summary

Study aim

• Selecting the best diuretic to treat congestive heart failure • Reduction the symptoms of patients with congestive heart failure

Design

Clinical trial with control group and intervention group, double blind, randomized, phase 2-3 on 180 patients. The website http://www.randomization.com will be used for randomization.

Settings and conduct

The studied samples are selected from among 180 patients with congestive heart failure on the last day of their hospitalization and after completing the informed consent form and taking into account the inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient consent for participation in the study. Suffering from congestive heart failure. Having NYHA class of 2, 3, or 4. Exclusion criteria: Suffering from severe hypokalemia. Glomerular filtration rate less than 15. Having chronic obstructive pulmonary disease. Left ventricular ejection fraction above 40%. Diastolic dysfunction grade Ⅱ or higher. Uric acid above 10 mg/dL.

Intervention groups

Control group: Including 90 patients with congestive heart failure who will take diuretic furosemide 20 mg three times a day and one tablet each time and placebo one tablet daily. Intervention group: Including 90 patients with congestive heart failure who will take diuretic furosemide 20 mg three times a day and one tablet each time, and also will take diuretic indapamide 1.5 mg daily.

Main outcome variables

Reducing congestion and evaluation of electrolyte disorders

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220809055644N1**
Registration date: **2022-10-12, 1401/07/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-12, 1401/07/20**
Update count: **0**

Registration date

2022-10-12, 1401/07/20

Registrant information

Name

Amir Aris

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

aris_amir@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation the efficacy of diuretic therapy with furosemide compared with combined diuretic therapy with furosemide and indapamide in treatment of patients with congestive heart failure: A randomized clinical trial

Public title
"Efficacy of diuretic therapy with furosemide compared with combined diuretic therapy with furosemide and indapamide in treatment of congestive heart failure"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
"Suffering from congestive heart failure" " NYHA class of all participants is 2,3, or 4" " Willingness to participate in the study"

Exclusion criteria:
"Severe hypokalemia" "Glomerular filtration rate (GFR) less than 15 ml/min" "Suffering from chronic obstructive pulmonary disease(COPD)" "LVEF more than 40 %" "Diastolic dysfunction grade Ⅱ and above" "Uric acid above 10 mg/dL"

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description
The website http://www.randomization.com/ will be used for randomization. The randomization of this study will be by the blocked randomization method. Based on the list of codes obtained from this website, each patient will be randomly assigned to the intervention or control group using blocks of 4 in a ratio of 1:1. For concealment, a code will be assigned to each patient and each of the randomly generated codes will be written on a card. Then they will be placed inside sealed opaque envelopes in random order. In order to maintain the random sequence, the outer surface of the envelopes will be numbered in the same order. Finally, the lid of the letter envelopes will be glued and will be placed in a box respectively. At the time of sampling, one of the envelopes will be determined according to the opening order and the assigned group of that participant.

Blinding (investigator's opinion)
Double blinded

Blinding description
For the purpose of blinding, placebos completely identical in terms of color, smell, shape and size to indapamide drug will be prepared for this study. The indapamide drug used for the patients of this plan will also be provided to the patients without any label (only if it is obvious to the person giving the medicine) in unlabeled cans and by the prescribing doctor. In this study, participants and Assessors are blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
Cardiovascular Diseases Research Center, Dr. Heshmat Heart Hospital, 15th of Khordad Street, Mosalla Square, Guilan, Rasht, Iran

City
Rasht

Province
Guilan

Postal code
4193955588

Approval date
2022-07-06, 1401/04/15

Ethics committee reference number
IR.GUMS.REC.1401.196

Health conditions studied

1

Description of health condition studied
Congestive heart failure

ICD-10 code
150.0

ICD-10 code description
Congestive heart disease

Primary outcomes

1

Description
Assessment symptoms of congestion

Timepoint
At the beginning of the study (before the start of the intervention), one month and three months after the start of taking the studied diuretics.

Method of measurement
Physical examination of the patient in terms of congestion

2

Description
Evaluation of electrolyte disorders
Timepoint
Before the intervention, 1 month and 3 months after the intervention
Method of measurement
Blood tests

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: It will include 90 patients with congestive heart failure. In addition to the daily consumption of furosemide 20 mg three times a day, one pill each time, the intervention group will also take the diuretic indapamide 1.5 mg once a day. This group will take furosemide and indapamide diuretics for three months.
Category
Treatment - Drugs

2

Description
Control group: Control group: Including 90 patients with congestive heart failure. For the participants in the control group, the diuretic furosemide will be prescribed along with placebo. In this way, the patients of this group will take furosemide 20 mg three times a day, one tablet each time, and placebo one tablet a day. This group will take furosemide and placebo for three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Heshmat heart Hopital
Full name of responsible person
Amir Aris
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
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Street address
Deputy of Research and Technology of Guilan University of Medical Sciences- in front of 17 Shahrivar Hospital – Shahid Siadati Ave. ,Namjoo St. ,Rasht, Iran
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Oia.int@gums.ac.ir
Web page address
https://research.gums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Amir Aris
Position
Associate professor
Latest degree
Specialist

Other areas of specialty/work
Cardiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
"No more information"
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Parts of the data, such as information related to the main outcomes can be shared
When the data will become available and for how long
"Starting the access period 2 years after the results are published"
To whom data/document is available
Researchers of the study
Under which criteria data/document could be used
Journal if needed
From where data/document is obtainable
Amir Aris
What processes are involved for a request to access data/document
Request for data should be sent via email to Dr. Amir Aris.
Comments