

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

+98 13 3361 8177

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

I50.0

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

Street address

Dr. Heshmat Heart Hospital, 15th of Khordad Street, Mosalla Square, Guilan, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

4193955588

Phone

+98 13 3361 8177

Fax

+98 13 3366 8718

Email

aris_amir@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

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

City

Rasht

Province

Guilan

Postal code

4193955588

Phone

+98 13 3333 5821

Fax

+98 13 3333 6395

Email

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

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

Phone

009833618177

Fax

+98 13 3366 8718

Email

aris_amir@yahoo.com

Person responsible for scientific 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

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

Phone

+98 13 3361 8177

Fax

+98 13 3366 8718

Email

aris_amir@yahoo.com

Person responsible for updating data**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

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

Phone

+98 13 3361 8177

Fax

+98 13 3366 8718

Email

aris_amir@yahoo.com

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