Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Comparing the impact of Metolazone plus Furosemide versus Hydrochlorthiazide Plus Furosemide in Patients with Heart failure and refractory edema: A Randomized clinical trial.

Protocol summary

Study aim
Comparison of Metolazone/Furosemide with Hydrochlorothiazide/Furosemide on diuretic resistance break and improving clinical symptoms.

Design
Clinical trial with control group, with parallel group design, not blind, randomized, phase 1-2, with a sample size of 50 patients. Randomization was performed as a systematic randomization by numbers obtained from GraphPad online software considering 2 groups of 25 people (intervention and control) by an independent person.

Settings and conduct
The study site was the VIP section of the Shahid Madani Research and Treatment Center in Tabriz. There will be no blinding in the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with diastolic heart failure and refractory edema; age of 18-80 years old; GFR>30; Filling the consent form. Non-inclusion criteria: Renal dysfunction (creatinine clearance of <30 ml/min); History of end-stage renal failure or dialysis; Contraindications for Metolazone and Hydrochlorothiazide; Cardiogenic shock; Acute myocardial infarction; Hypoalbuminemia

Intervention groups
Intervention group will Metolazone 2.5 and patients in the control group will receive only routine treatment.

Main outcome variables
Edema; Fluid Input/Output; Sodium (Na); Potassium (K)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111206008307N35**
Registration date: **2020-07-25, 1399/05/04**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-25, 1399/05/04**
Update count: **0**

Registration date
2020-07-25, 1399/05/04

Registrant information

Name
Taher Entezari-Maleki

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-26, 1398/09/05

Expected recruitment end date
2020-10-21, 1399/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the impact of Metolazone plus Furosemide versus Hydrochlorthiazide Plus Furosemide in Patients with Heart failure and refractory edema: A Randomized clinical trial.

Public title
The effect of Metolazone and Hydrochlorothiazide in refractory edema
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with diastolic heart failure and refractory edema Glomerular l filtration rate (GFR) > 30
Exclusion criteria:
Renal dysfunction (creatinine clearance <30 ml/min) History of end-stage renal failure or dialysis Acute myocardial infarction Cardiogenic shock Contraindications for metolazone and hydrochlorothiazide Hypoalbuminemia Patients who are not satisfied
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **50**
More than 1 sample in each individual
Number of samples in each individual: **1**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was done using computer generated random number (systematic randomization) by online Graphpad software by determining 2 study groups and 25 patients in each group (Control and Intervention) by an independent person.
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
Ethic Committee of Tabriz Univercity of Medical Science
Street address
Reasearch and Technology Deputy, Tabriz University of Medical Science, Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2019-11-26, 1398/09/05
Ethics committee reference number
IR.TBZMED.REC.1398.895

Health conditions studied

1

Description of health condition studied
Systolic and diastolic heart failure
ICD-10 code
I50.4
ICD-10 code description
Combined systolic (congestive) and diastolic (congestive) heart failure

Primary outcomes

1

Description
Fluid Input/Output
Timepoint
Daily
Method of measurement
Urine bag

2

Description
Sodium (Na)
Timepoint
Daily
Method of measurement
Laboratory test

3

Description
Edema
Timepoint
Daily
Method of measurement
Physical examination

4

Description
Potassium (K)
Timepoint
Daily
Method of measurement
Laboratory test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Will receive furosemide with Metolazone one 2.5 mg tablet daily, product of Teofarma Pharmaceutical Company, until improving clinical symptoms.
Category
Treatment - Drugs

2

Description
Control group: Will only receive standard treatments (Hydrochlorothiazide with Furosemide).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Heart Center of Tabriz
Full name of responsible person
Dr. Taher Entezari-Malek
Street address
Shahid Madani Heart Center, Daneshghah Street, Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Mohammad Samiei
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Golgasht, Daneshghah street, Tabriz
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5165665931
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Samiei.moh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Taher Entezari-maleki
Position
Associated professor of Clinical pharmacy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All of the data of an article can be published after making patients unrecognized.

When the data will become available and for how long
After publishing of article until 6 months after publishing of the results

To whom data/document is available
Data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
Researchers that request data will be permitted only to doing analysis according to ethics for scientific aims.

From where data/document is obtainable
Applicants can receive data by sending an E-mail to address of tentezari@gmail.com and get response from Dr. Taher Entezari Maleki.

What processes are involved for a request to access data/document
After contacting with corresponding author(Dr.Taher Entezari Maleki), data will be sent to Tabriz Shahid Madani hospital ethics committee and after receiving permission, data will be send to applicants.

Comments