Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The impact of Triamterene-Hydrochlorothiazide plus Furosemide versus Hydrochlorothiazide plus Furosemide in patients with heart failure and Refractory edema: A randomized clinical trial.

Protocol summary

Study aim

1. Comparison of Triamterene-H/Furosemide with Hydrochlorothiazide/Furosemide on diuretic resistance failure.

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

This is a randomized clinical trial on a total of 50 patients over 18 years with heart failure and refractory edema who attended the Shahid Madani clinic of Tabriz University of Medical Science. Intervention group will recieve Triamterene-H 50/25 product of Sobhan Pharmaceutical Company in addition to routine treatment. Patients in the control group will receive only routine treatment. Patients will compare regarding edema and fluid Input/Output and Na and K levels in both groups using SPSS by appropriate statistical tests.

Participants/Inclusion and exclusion criteria

Inclusion: 1.Patients with heart failure and refractory edema 2.age 18-80 3.GFR>30 4.Filling the consent form Exclusion: 1.Renal dysfunctin (creatinine clearance of <30 ml/min) 2.History of end-stage renal failure or dialysis 3.Contraindications for Triamterene-H and Hydrochlorothiazide 4.Cardiogenic shock 5.Acute myocardial infarction 6.Hypoalbuminemia

Intervention groups

Intervention group will recieve 25mg Triamterene (in Triamterene-H tablets) plus routine treatment and patients in the control group will receive Furosemide/Hydrochlorothiazide (routine treatment).

Main outcome variables

1) Edema 2) Fluid Input/Output 3) Measurement Na and K

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111206008307N37**
Registration date: **2020-08-21, 1399/05/31**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-21, 1399/05/31**
Update count: **0**

Registration date

2020-08-21, 1399/05/31

Registrant information

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Taher Entezari-Maleki
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Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-21, 1398/07/29

Expected recruitment end date

2020-10-20, 1399/07/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The impact of Triamterene-Hydrochlorothiazide plus Furosemide versus Hydrochlorothiazide plus Furosemide in patients with heart failure and Refractory edema: A randomized clinical trial.

Public title
Comparison of Triamterene-hydrochlorothiazide and Hydrochlorothiazide in refractory edema
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with systolic and diastolic heart failure and refractory edema GFR > 30
Exclusion criteria:
Renal dysfunctin (creatinine clearance of <30 ml/min) History of end-stage renal failure or dialysis Cardiogenic shock Acute myocardial infarction Hypoalbuminemia Any contraindications for Triamterene-Hydrochlorothiazide and Hydrochlorothiazide 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: **25**
Intervention group will receive 25 mg Triamterene (in Triamterene-H(Hydrochlorothiazide)) tablets daily plus standard treatment and control group will only receive standard treatment (Furosemide/Hydrochlorothiazide) daily.
Randomization (investigator's opinion)
Randomized
Randomization description
Simple 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. The software randomly divided 50 patients into two groups of A(control) and B(intervention).
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
2019-10-21, 1398/07/29
Ethics committee reference number
IR.TBZMED.REC.1398.735

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 from admission day to discharge day
Method of measurement
Urine bag

2

Description
Measurement of Na and K
Timepoint
Daily from admission day to discharge day
Method of measurement
Laboratorial

3

Description
Edema

Timepoint
Daily from admission day to discharge day
Method of measurement
Physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Will receive 25 mg Triamterene (in combination of Triamterene-H tablets product of Sobhan Pharmaceutical Company) daily plus standard treatment (Furosemide/Hydrochlorothiazide) until improvement of clinical symptoms.
Category
Treatment - Drugs

2

Description
Control group: Will only recieve standard treatments (Furosemide/Hydrochlorothiazide).
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-Maleki
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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 town
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Samiei.moh@gmail.com
Web page address
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 scientific

inquiries

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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