

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 receive 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 dysfunction (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 receive 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

Name

Taher Entezari-Maleki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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tentezarimaleki@razi.tums.ac.ir

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 dysfunction (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 University of Medical Science

Street address

Research 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 receive 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

Street address

Shahid Madani Heart Center, Daneshghah Street, Tabriz

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+98 41 3334 4798

Email

tentezari@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Samiei

Street address

Golgasht, Daneshghah street, Tabriz town

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3335 7310

Email

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

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific

inquiries

Contact

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Full name of responsible person

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Position

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Other areas of specialty/work

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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

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Taher Entezari-Maleki

Position

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Latest degree

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Other areas of specialty/work

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