

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

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

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

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

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

Update count: **0**

#### Registration date

2020-07-25, 1399/05/04

#### 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.

#### Registrant information

##### Name

Taher Entezari-Maleki

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6695 4709

##### Email address

tentezarimaleki@razi.tums.ac.ir

#### 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.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### 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

#### 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

#### Intervention groups

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

#### Scientific title

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

#### 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**

**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 I 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 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**

2019-11-26, 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, Daneshgah Street, Tabriz

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614766

#### Phone

+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, Daneshgah street, Tabriz

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5165665931

#### Phone

+98 41 3335 7310

### Email

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

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

Shahid Madani Center, Daneshgah Street,Tabriz

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## Person responsible for scientific 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

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Taher Entezari-Maleki

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Associated professor of Clinical pharmacy

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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 sent to applicants.

**Comments**