

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Intravenous Hypertonic saline solution in management of patients with Diuretic Resistant Generalized Edema

#### Protocol summary

##### Study aim

Evaluation of Intravenous Hypertonic saline infusion in treatment of patients with Diuretic Resistant Generalized Edema

##### Design

This is a randomized, double-blinded clinical trial performed on patients admitted to Imam Hossein Hospital. All participants were evaluated carefully with clinical history, physical examination. Fasting blood samples were drawn to determine serum levels of Na, K, Cl, creatinine, urea, Urinary osmolarity and C-cystatin before and 48 hours after treatment. The body weight of patients assessed in the morning, Digital Scales, before and 48 hours after management.

##### Settings and conduct

The first one intervention group received 150 ml of hypertonic sodium 3% and 250 mg of furosemide every 12 hours for 48 hours and the second placebo group received normal serum saline 0.9% instead of hypertonic. The change in the Body weight, urine output, blood pressure, uric acid, Urine osmolarity, blood biochemistry features and C-cystine levels were assessed.

##### Participants/Inclusion and exclusion criteria

The target population for this trial was patients older than 18 years old with diffuse peripheral edema who did not respond adequately to receive 80 mg of furosemide. Subjects candidated of hemodialysis, systolic pressure  $\leq 80$  mmHg, GFR  $\leq 15$ , serum albumin  $\leq 2.5$ , serum potassium  $\geq 5.5$ , serum sodium more than 145, and anuric patients (urine volume  $\leq 100$  ml per 24 hours). Patients with comorbidities, as dementia, cerebral vascular disease and inability to give informed consent were excluded, as were patients requiring pacemaker implantation and those with a substance or alcoholic addiction.

##### Intervention groups

patient with generalized resistant to diuretic edema who will undergo treatment with 250 mg furosemide plus 150

cc 3% saline q 12h for 48h

##### Main outcome variables

weight c-cystatine

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200812048380N1**

Registration date: **2020-10-10, 1399/07/19**

Registration timing: **prospective**

Last update: **2020-10-10, 1399/07/19**

Update count: **0**

##### Registration date

2020-10-10, 1399/07/19

##### Registrant information

##### Name

Mahshad Ghoddusi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7745 0199

##### Email address

mahshad.ghoddusi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-04, 1399/10/15

##### Expected recruitment end date

2021-06-05, 1400/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Intravenous Hypertonic saline solution in management of patients with Diuretic Resistant Generalized Edema

**Public title**  
Intravenous Hypertonic saline solution in management of patients with Diuretic Resistant Generalized Edema

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
The target population for this trial was patients older than 18 years old with diffuse peripheral edema who did not respond adequately to 80 mg oral furosemide.  
**Exclusion criteria:**  
subjects candidate for hemodialysis systolic blood pressure  $\leq 80$  mmHg GFR  $\leq 15$  ml/min serum albumin  $\leq 2.5$  g/dL serum potassium  $\geq 5.5$  mEq/L serum sodium greater than 145 mEq/L anuric patients (urine volume  $\leq 100$  ml per 24 hours)

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **28**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Personal plane randomization The method of assigning the subjects after applying the entry and exit criteria will be random allocation by permutation block method. The randomization unit is individual. The size of the blocks is 4 and in each block, each intervention group will be repeated twice. As a result, we will have 7 different blocks. Then, using the statistical program in R software version 3.6.1, 7 blocks of 4 will be produced, which will produce a total of 28 sequences. Using this randomly generated list, participants are assigned to one of two study groups.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Double blinded (patients and health care providers are kept blinded) Patients don't know about the groups but they are aware of treatment process. People who assess the study are not aware of patients group

**Placebo**  
Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

SBMU morality committee

##### Street address

No.39, Paryab Ave., Takavaran St., Delavaran Blvd., Resalat Sq.

##### City

Tehran

##### Province

Tehran

##### Postal code

1688937481

#### Approval date

2018-05-12, 1397/02/22

#### Ethics committee reference number

IR.SBMU.retech.rec.1397.520

## Health conditions studied

### 1

#### Description of health condition studied

GENERALIZED EDEMA RESISTANT TO THERAPY

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

weight loss

#### Timepoint

daily

#### Method of measurement

scale

### 2

#### Description

serum cr

#### Timepoint

before and after treatment

#### Method of measurement

blood sample

### 3

#### Description

c systatin

#### Timepoint

before and after treatment  
**Method of measurement**  
blood sample

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: they will undergo with treatment by 250mg fursomide q12h plus 150cc normal saline for 48 hours

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: they will undergo with treatment by 250mg fursomide q12h plus 150cc hypertonic saline 3% for 48 hours

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran Imam Hossein Hospital

##### Full name of responsible person

Mahshad Ghoddusi

##### Street address

Madani st.

##### City

tehran

##### Province

Tehran

##### Postal code

1617763141

##### Phone

+98 21 7343 0000

##### Email

info@ehmc.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Seyed Ali Ziaee PHD

##### Street address

Arabi st., Daneshjou Blvd., Velenjak

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 23871

##### Email

info@sbmu.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahid Beheshti University of Medical Sciences

#### Proportion provided by this source

60

#### 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

Tehran University of Medical Sciences

##### Full name of responsible person

Mahshad Ghoddusi

##### Position

nephrology fellowship

##### Latest degree

Specialist

##### Other areas of specialty/work

Internal Medicine

##### Street address

No. 39. Paryab ave., Takavaran st., Delavaran blvd., reslaat sq

##### City

Tehran

##### Province

Tehran

##### Postal code

1688937481

##### Phone

+98 21 7745 0199

##### Email

mahshad.ghoddusi@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mahshad Ghoddusi

**Position**

nephrology fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

No.39., Paryab ave., Takavaran st.,Delavaran Blvd.

resalat sq

**City**

tehran

**Province**

Tehran

**Postal code**

1688937481

**Phone**

+98 21 7745 0199

**Email**

mahshad.ghoddusi@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mahshad Ghoddusi

**Position**

nephrology fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

No. 39, Paryab ave., Takavaran st.,Delavaran st.,

Reslat sq

**City**

tehran

**Province**

Tehran

**Postal code**

1688937481

**Phone**

+98 21 7745 0199

**Email**

mahshad.ghoddusi@gmail.com

**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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Data are available as questionnaires

**When the data will become available and for how long**

since data gathering

**To whom data/document is available**

guidance professors

**Under which criteria data/document could be used**

as they requested

**From where data/document is obtainable**

mahshad ghoddusi MD 09126098165

**What processes are involved for a request to access data/document**

request by phone

**Comments**