Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 ≤80 mmHg, GFR ≤15, serum albumin ≤2.5, serum potassium ≥5.5, serum sodium more than 145, and anuric patients (urine volume ≤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 duretic edema who will undergo treatment with 250 mg fursomide 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 ≤80 mmHg GFR ≤15ml/min serum albumin ≤2.5g/dL serum potassium ≥5.5mEq/L serum sodium greater than 145mEq/L anuric patients (urine volume ≤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 dont 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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

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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

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 questionares

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