

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluating the effect of hypertonic saline in edema of ICU patients

Protocol summary

2020-01-01, 1398/10/11

Study aim

Evaluating the effect of hypertonic saline in edema of ICU patients

Design

Two arm parallel group randomized trial (control and intervention groups), blinded and outcome assessment

Settings and conduct

Admission patients that have 2+ edema or more in ICU of Imam Hossein Hospital in Tehran are divided into two intervention and control groups and evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Admission patients in ICU who have more than 18 years old, Patients that have 2+ edema or more
Exclusion criteria: Sodium more than 155, Hemodialysis patients, Albumin less than 2 mg/dl , Creatinine equal to or more than 1.5 mg/dl , Norepinephrine dependent blood pressure, Blood pressure more than 180/100 ,

Intervention groups

According to treatment protocols for patients with edema, the furosemide ampoule is given as a 30-minute infusion. In our study, the control group received the standard treatment and patients in the intervention group received furosemide ampoule plus hypertonic saline.

Main outcome variables

Urine volume, level of edema, APACHE II score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191115045446N1**

Registration date: **2020-01-01, 1398/10/11**

Registration timing: **prospective**

Last update: **2020-01-01, 1398/10/11**

Update count: **0**

Registration date

Registrant information

Name

Samin Salehi jazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8856 3910

Email address

saminsalehi58@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-03, 1398/10/13

Expected recruitment end date

2020-07-03, 1399/04/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of hypertonic saline in edema of ICU patients

Public title

Evaluating the effect of hypertonic saline in edema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Admission patients in ICU who have more than 18 years old Patients that have 2+ edema or more

Exclusion criteria:

Sodium more than 155 Albumin less than 2 mg/dl Creatinine equal to or more than 1.5 mg/dl Hemodialysis

patients Blood pressure more than 180/100
Norepinephrine dependent blood pressure

Age

From 18 years old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 32

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization: A random number table was created by using Excel software and using the RND command.

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

بیمارستان امام حسین

Street address

Shahid Madani street

City

Tehran

Province

Tehran

Postal code

1991953381

Approval date

2019-07-15, 1398/04/24

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.106

Health conditions studied

1

Description of health condition studied

Generalized edema

ICD-10 code

R60.1

ICD-10 code description

Generalized edema

Primary outcomes

1

Description

Patients in Intensive care unit with 2+ edema or more

Timepoint

entrance to study and 2 days after intervention

Method of measurement

Measuring of urine volume and edema

Secondary outcomes

1

Description

APACHE II score

Timepoint

entrance to study

Method of measurement

APACHE II score

Intervention groups

1

Description

Intervention group: receiving 50 ml Hypertonic saline and 20 mg Furosemide TDS for 48 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

بخش مراقبت های ویژه بیمارستان امام حسین

Full name of responsible person

محمد سیستانی زاد

Street address

تقاطع نیایش و ولیعصر, دانشکده داروسازی دانشگاه علوم پزشکی شهید بهشتی, گروه داروسازی بالینی

City

تهران

Province

Tehran

Postal code

1985717443

Phone

+98 21 7343 2309

Email

sistanizadm@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Tahereh shams

Street address

Velenjak Street, Shahid Chamran High Way

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 23 87121

Fax

+98 21 8887 3794

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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Sistanizad

Position

Associated Professor/ Clinical Pharmacy Specialist

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98218800087

Email

sistanizadm@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Sistanizad

Position

Associated Professor, Clinical Pharmacy Specialist

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98218800087

Email

sistanizadm@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Samin Salehi

Position

Pharmacy student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Niayesh Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8856 3910

Email

saminsalehi58@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available