Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of hypertonic and normal saline on the success of resuscitation in patients with septic shock during the first three hours of treatment

Protocol summary

Study aim

Reducing the effects of septic shock with early treatment with hypertonic saline.

Design

Clinical trial with control group,with parallel groups,double-blind,randomized, phase 3 on 52 patients.For randomization based on a random sequence created from www.randomization.com and the order in which patients enter the study, they will be included in the control or intervention group.

Settings and conduct

Using random sampling and intensive care units, patients with severe sepsis are randomly divided (using closed envelopes) into two groups of control and intervention. Optical nerve diameter and hemodynamic parameters and gasometric parameters in the first and second hours The third treatment is recorded for comparison between the two groups. The subjects and the treating physician will be unaware of the intervention and control groups (double-blind)

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patients with septic shock, age between 18-80 years Exclusion criteria:Patient dissatisfaction,patients with incurable disseminated malignancy,patients with hyperthermia,patients receiving colloidal solutions and any volume limitation restrictions.

Intervention groups

In the intervention group, 5% hypertonic saline is prescribed at the beginning of septic shock treatment. In the control group, conventional resuscitation (isotonic saline serum) is performed. In both groups, optic nerve diameter is measured by ultrasound before saline administration (without placebo).

Main outcome variables

Hemodynamic parameters (HR, SBP, DBP, MAP, CVP) and gasometric parameters (PH, PaCO2, PaO2, HCO3, BE, Lactate) and optic nerve diameter at the beginning of the study and in the first and second and third hours of intervention (optic nerve diameter At the beginning of the third hour of intervention), they are measured, recorded and compared.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111212008384N7**
Registration date: **2022-02-22, 1400/12/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-22, 1400/12/03**
Update count: **0**

Registration date

2022-02-22, 1400/12/03

Registrant information

Name

Arash Peivandi Yazdi

Name of organization / entity

Mashhad University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of hypertonic and normal saline on the success of resuscitation in patients with septic shock during the first three hours of treatment

Public title

Comparison of the effect of hypertonic and normal saline on the success of resuscitation in patients with septic shock

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with septic shock, Age between 80-18 years

Exclusion criteria:

Patient dissatisfaction, Patients with incurable disseminated malignancy, Patients with hypernatremia, Patients receiving colloidal solutions such as albumin, etc. Any volume-limiting restrictions such as irreversible heart failure

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**

More than 1 sample in each individual

Number of samples in each individual: **10**

The diameter of the optic nerve in both groups is measured and recorded by ultrasound before treatment and after 3 hours. Hemodynamic parameters (HR, SBP, DBP, MAP, CVP) and gasometric parameters during the first three hours of treatment are recorded for comparison in the two groups.

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining informed consent from the patient's first-degree relatives, patients are randomly divided into control and intervention groups (using sealed envelopes). For randomization based on a random sequence created from www.randomization.com and the order in which patients enter the study, they will be included in the control or intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The subjects and the treating physician will be unaware of the intervention and control groups

Placebo

Not used

Assignment

Parallel

Other design features

The diameter of the optic nerve in both groups is measured and recorded by ultrasound before treatment and after 3 hours.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ibn Sina St., Imam Reza Hospital, Building 610, Surgical ICU

City

mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2021-12-14, 1400/09/23

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.665

Health conditions studied

1

Description of health condition studied

Septic shock

ICD-10 code

R57.2

ICD-10 code description

R57.2

Primary outcomes

1

Description

Hemodynamic parameters (heart rate, mean arterial pressure, systolic blood pressure, diastolic blood pressure, central venous pressure)

Timepoint

At the beginning of the patient's study and in the first, second and third hours of the intervention

Method of measurement

Hemodynamic parameters by monitoring device andCentral venous pressure rulers are measured

Secondary outcomes

1

Description
1- Gasometric parameters 2- Optical nerve diameter
Timepoint
At the beginning of the patient's study and in the first, second and third hours of the intervention (optic nerve diameter at the beginning and the third hour of the intervention), they are measured, recorded and compared.
Method of measurement
Gasometer and sonography device

Intervention groups

1

Description
In the intervention group, 5% hypertonic saline is prescribed at the rate of 5 cc per kg of body weight at the beginning of septic shock treatment.
Category
Treatment - Drugs

2

Description
In the control group, conventional resuscitation is performed (initial targeted treatment with 30 cc of isotonic saline per kilogram of body weight during the first 3 hours of septic shock).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital of Mashhad
Full name of responsible person
Arash Peyvandi Yazdi
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Ibn Sina St., Imam Reza Hospital, Building 610, Surgical ICU
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Arash Peyvandi Yazdi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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