

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of Additive effect of sodium bicarbonate with early goal-directed therapy in the first three hours of hemodynamic management of patients with severe sepsis and septic shock in intensive care units of Imam Reza hospital, Mashhad

Protocol summary

Study aim

Investigating the increased possibility of stabilizing hemodynamics by restoring intravascular volumes along with the administration of sodium bicarbonate in the first 3 hours in severe sepsis and septic shock patients

Design

In this study, a triple blind clinical trial with parallel groups in phase 3, patients with severe sepsis or septic shock documented in the special care departments of Imam-Reza Hospital in Mashhad, randomly (blocked and in sealed envelopes) They are divided into two groups of 36 people, control and intervention.

Settings and conduct

The control group will receive the same conventional method of treatment (30 cc/kg of isotonic crystalloid serum during the first 3 hours) and in the intervention group, sodium bicarbonate will be administered at the rate of half of the deficit calculated to the same previous volume as the control group during 3 hours.

Participants/Inclusion and exclusion criteria

Patients with severe sepsis and septic shock aged between 18-80 years were included in the study and patients with non-satisfaction; patients with untreatable disseminated malignancy; patients with alkalotic gasometry; patients receiving sodium bicarbonate before admission; patients with hypernatremia; patients receiving colloidal solutions; and any type of volume restriction and sodium bicarbonate were excluded from the study.

Intervention groups

In the control group, the conventional method of resuscitation (Early Goal Directed Therapy) with 30 cc/kg of isotonic crystalloid serum during the first 3 hours, is performed (No placebo). In the intervention group, sodium bicarbonate is added to the volume of 30 cc/kg of same serum in the amount of half of the calculated

bicarbonate deficiency during the first three hours.

Main outcome variables

Hemodynamic and gasometric parameters are the primary outcomes at the time of entering the study and three hours after the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220310054246N1**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**

Update count: **0**

Registration date

2023-04-17, 1402/01/28

Registrant information

Name

Ehsan Noori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3602 8867

Email address

nourie981@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Additive effect of sodium bicarbonate with early goal-directed therapy in the first three hours of hemodynamic management of patients with severe sepsis and septic shock in intensive care units of Imam Reza hospital, Mashhad

Public title

Evaluation of Additive effect of sodium bicarbonate with early goal-directed therapy in management of patients with severe sepsis and septic shock

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with severe sepsis Patients with septic shock
Age between 18 and 80 years old

Exclusion criteria:

Dissatisfaction of patients Patients with incurable diffuse malignancy Patients with alkalotic gasometry Patients receiving sodium bicarbonate prior to study entry Patients with hypernatremia Patients receiving colloidal solutions Any type of limitation in the administration of volume and sodium bicarbonate

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed in a blocked manner. For this purpose, to prevent predictability of the next treatment, 15 blocks of 4 in the combination of letters A and B (ABAB, BAAB, BBAA, BABA, ABBA) and six double blocks were randomly selected and assigned to groups based on this division. Classification will be done. In order to hide the allocations, the type of treatment obtained will be placed in sealed envelopes and at the moment of treating the patients, their type of treatment will be revealed to the allocator of the sample into groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients and the analyst and allocator of the samples will be unaware of the intervention and control groups. In order to hide the allocations, the type of treatment obtained will be placed in sealed envelopes and at the moment of treating the patients, their type of treatment will be revealed to the allocator of the sample into groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghorashi Building, next to Hoveyzeh Cinema, Daneshgah St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2022-07-05, 1401/04/14

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.230

Health conditions studied**1****Description of health condition studied**

Severe sepsis and septic shock

ICD-10 code

R57.8

ICD-10 code description

Other shock

2**Description of health condition studied**

Metabolic acidosis

ICD-10 code

E87.2

ICD-10 code description

Acidosis

Primary outcomes

1

Description

Investigating the possibility of increased stability of hemodynamic parameters such as blood pressure and heart rate

Timepoint

Before the intervention and three hours later

Method of measurement

Cardiac monitoring device

2

Description

Investigating the possibility of improving gasometric parameters such as acidity and sodium bicarbonate

Timepoint

Before the intervention and three hours later

Method of measurement

Performing gasometry of arterial blood samples in a laboratory manner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sodium bicarbonate solution with a concentration of 7.5% in the amount of half of the deficiency calculated by the method ($\text{weight} \times \text{base} \times 0.3$) will be added to the liquid volume calculated in the amount of 30 cc of isotonic crystalloid serum per kilogram of body weight in 3 hours.

Category

Treatment - Drugs

2

Description

Control group: The calculated volume of liquid is 30 cc of isotonic crystalloid serum per kilogram of body weight in 3 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Ehsan Noori

Street address

Ebne Sina St

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Fax

+98 51 3854 3031

Email

b.emamreza@mums.ac.ir

Web page address

<https://emamreza.mums.ac.ir/index.php>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid ghayour mobarhan

Street address

Ghorashi Building, next to Hoveyze Cinema, Daneshgah St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

Ghayourem@mums.ac.ir

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

Ehsan Noori

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Ebne Sina St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Fax**Email**

nourie981@mums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Arash Peivandi Yazdi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Ebne Sina St

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 5261

Email

peivandia@mums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Ehsan Noori

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Ebne Sina St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Fax**Email**

nourie981@mums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available