Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 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 (weight*base base*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 Hoveyzeh 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