

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Investigating the effects of zinc sulfate and vitamin C supplementation in sepsis management in septic patients

Protocol summary

Study aim

Evaluation of the effects of vitamin C and zinc supplementation on mortality rate in patients with sepsis

Design

This is a randomized, double-blinded, parallel, two-armed, Single Center, Phase 3 clinical trial. Randomization will be done with block randomization method by the use of www.sealedenveloped.com. 60 patients with eligible criteria, will enrolled in study and randomly assigned to either intervention or control group.

Settings and conduct

Patients who will admitted to Baqiatallah hospital and will meet the eligible criteria, will be enrolled to study, and will randomly assigned in either intervention or placebo group, and will receive the drug/placebo for 10 days. This study is a double-blinded clinical trial, in which prescribed physician and statistical analyzer will be unaware of type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having suspected or proven infections; Increasing 2 points or more in SOFA compared to baseline; The patient or his/her guardian has informed and free written consent to participate in the study. Exclusion criteria: Multi organ dysfunction; Glasgow Coma Score (GCS) less than 4; The patient needs emergency dialysis due to severe acidosis or end stage renal disease; Pregnancy; Breastfeeding; Being NPO for any reasons; Having kidney stones as his/her medical history; Having hypersensitivity reactions history with the intervention.

Intervention groups

Intervention group : sachet contains 300 mg of vitamin C and 10 mg of zinc (produced by "Bonyan-Salamat-Kasra" company); every 12 hours, 7 sachet, per oral, for 10 days. Control group : Placebo sachet with Placebo sachet with a appearance quite similar to the original drug, every 12 hours, 7 sachet, per oral, for 10 days.

Main outcome variables

Mortality rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001165N67**

Registration date: **2022-02-26, 1400/12/07**

Registration timing: **prospective**

Last update: **2022-02-26, 1400/12/07**

Update count: **0**

Registration date

2022-02-26, 1400/12/07

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of zinc sulfate and vitamin C supplementation in sepsis management in septic patients

Public title

Investigating the effects of zinc sulfate and vitamin C supplementation in sepsis management in septic patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having suspected or proven infection; Increasing 2 points or more of SOFA score compared to the baseline; The patient or his/her guardian has informed and free written consent to participate in the study;

Exclusion criteria:

Multi organ dysfunction; Glasgow Coma Score (GCS) less than 4; The patient needs emergency dialysis due to severe acidosis or end stage renal disease; Pregnancy; Breastfeeding; Being NPO for any reasons; Having kidney stones as his/her medical history; Having hypersensitivity reactions with the intervention in the past;

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method is used for randomization (To do this, go to www.sealedenvelope.com and select the randomization tab and then create a list). Due to the two arms of the study and the sample size, the size of the blocks will be considered as 4, and finally a random list of how the patients are arranged in the two groups will be provided 2 groups .

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study in which the prescribing physician and statistical analyzer will unaware of the type of intervention (placebo or drug). The prepared placebo is completely similar in appearance to the main medicine.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Islamic Azad University of Medical Sciences

Street address

Islamic Azad University Tehran Medical Sciences, Zargandeh St., Dr. Shariati St.

City

Tehran

Province

Tehran

Postal code

1949635881

Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

IR.IAU.TMU.REC.1400.217

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

Sepsis, unspecified organism

ICD-10 code

A41.9

ICD-10 code description

Sepsis, unspecified organism

Primary outcomes**1****Description**

30-days Mortality rate;

Timepoint

Daily, till 30 days.

Method of measurement

Vital signs assessment

Secondary outcomes**1****Description**

Length of ICU stay

Timepoint

Daily, until the discharge or death

Method of measurement

Medical record assessment

2

Description

Length of hospital stay

Timepoint

Daily, until the discharge or death

Method of measurement

Medical record assessment

3

Description

Vasopressor dose

Timepoint

Day 1, 5 and 10

Method of measurement

Check the medication list

4

Description

SOFA score changes

Timepoint

Day 1, 5 and 10

Method of measurement

Sequential Organ Failure Assessment(SOFA) score

Intervention groups

1

Description

Intervention group: Oral sachet, contains 300mg vitamin C and 10mg Zinc (produced by Bonyan-Salamat-Kasra company), 7 sachets, every 12 hours, PO for 10 days.

Category

Treatment - Drugs

2

Description

Control group: Oral placebo sachet with a quite similarity with intervention sachet (produced by Bonyan-Salamat-Kasra company), 7 sachets, every 12 hours, PO for 10 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiatallah hospital

Full name of responsible person

Seyed Jalal Madani

Street address

Baqiatallah hospital, Mollasadra St, Vanak Sq.

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1435916471

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Dr.jalalmadani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Gholamhosein Alishiri

Street address

Baqiyatallah University of Medical Science, south Sheikh-Bahaei St., Mollasadra St., Vanak Sq.

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R.bmsu@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bagheiat-allah 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

Tehran University of Medical Sciences

Full name of responsible person

Parisa Kianpour

Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

Fellowship of critical care pharmacotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Yunas Panahi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Critical care pharmacotherapy

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Person responsible for updating data

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Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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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