

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effects of zinc supplementation in patients with sepsis: a clinical trial

Protocol summary

Study aim

Determining the additive effects of zinc supplementation compared to placebo in sepsis patients in the intensive care unit

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 56 patients.

Settings and conduct

The study is a randomized controlled clinical trial intervention on patients with sepsis who are admitted to the special care units of Shariati Hospital for 7 days, with zinc supplement and control with placebo.

Participants/Inclusion and exclusion criteria

criteria of inclusion: 1. Age over 18 years 2. A patient admitted to the intensive care unit 3. A patient with sepsis 4. Patients under enteral nutrition (nasal, mouth, stomach) criteria of exclusion: 1. Pregnancy or breastfeeding 2. Body mass index over 35 (severe obesity) 3. Acquired immunodeficiency virus (HIV) disease 4. Patients at the time of transplantation 5. Patients with orders not to receive any type of enteral nutrition 6. Patients participating in other studies

Intervention groups

Patients in the intervention group will be given a zinc supplement containing 30 mg of elemental zinc. In the control group, the placebo will be similar in terms of shape and composition, with the only difference in the absence of the element. During the 7 days, patients will receive 1 zinc supplement tablet in the intervention group and placebo in the control group.

Main outcome variables

mNUTRIC, SOFA questionnaire score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220208053971N3**
Registration date: **2023-06-10, 1402/03/20**

Registration timing: **prospective**

Last update: **2023-06-10, 1402/03/20**

Update count: **0**

Registration date

2023-06-10, 1402/03/20

Registrant information

Name

Hamed Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

hmohamadi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-21, 1402/04/30

Expected recruitment end date

2024-04-18, 1403/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of zinc supplementation in patients with sepsis: a clinical trial

Public title

Investigating the effects of zinc supplementation in patients with blood infection

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years patient admitted to the intensive care unit patient with sepsis Patients under enteral nutrition (nasal, mouth, stomach)

Exclusion criteria:

Pregnancy or breastfeeding Body mass index over 35 (severe obesity) Human immunodeficiency virus (HIV) disease Patients at the time of transplantation Patients with orders not to receive any type of enteral nutrition Patients participating in other studies

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by stratified permute block randomization method in two strata based on (age and sex) using the website www.sealedenvelope.com. In this method, randomization will be done based on 28 blocks of 2, which is suitable for a sample size of 56 people with two intervention and control groups. Within each class, patients will be randomly assigned to one of the two study groups in a ratio of 1:1.

Blinding (investigator's opinion)

Double blinded

Blinding description

All subjects and their companions and researchers and healthcare personnel who are responsible for the care of patients will be unaware of the existing grouping until the end of the study; In such a way, the researcher and the person who takes the sample, like the study participants, are unaware of which patients are receiving zinc supplements or placebo. Patients and their companions are also unaware of the type of pill received. Drugs and placebos are coded by a person who is completely unaware of the study process, and this code is placed in an envelope that indicates whether it is a drug or a placebo code. One group will receive drug A and one group will receive drug B. Also, pills containing zinc supplements and placebo, which have the same color, smell, and size with the same shape, will be used. Hence, this study will be a double-blind study. Placebo tablets contain starch and are completely similar to zinc supplement tablets in terms of color, appearance and smell. Placebo tablets are also prepared by the same company that manufactures the placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shariati Hospital - Tehran University of Medical Sciences (Research Ethics Committee)

Street address

Karegar Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2023-05-07, 1402/02/17

Ethics committee reference number

IR.TUMS.SHARIATI.REC.1402.026

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

sepsis

ICD-10 code

A41.9

ICD-10 code description

Sepsis, unspecified organism

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

Sequential Organ Failure Assessment

Timepoint

The effect of zinc supplementation on the SOFA score at the beginning of the study (before the intervention) and 1 week after the intervention in patients with sepsis in the intensive care unit

Method of measurement

SOFA questionnaire score

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

28-day mortality

Timepoint

The effect of zinc supplementation on the 28-day mortality at the beginning of the study (before the

intervention) and 1 week after the intervention in patients with sepsis in the intensive care unit

Method of measurement
questionnaire

2

Description

Inflammatory factors

Timepoint

The effect of zinc supplementation on the Inflammatory factors at the beginning of the study (before the intervention) and 1 week after the intervention in patients with sepsis in the intensive care unit

Method of measurement

blood test

3

Description

nutritional status

Timepoint

The effect of zinc supplementation on the nutritional status at the beginning of the study (before the intervention) and 1 week after the intervention in patients with sepsis in the intensive care unit

Method of measurement

mNUTRIC questionnaire score

Intervention groups

1

Description

Intervention group: The patients in the intervention group will be given a zinc supplement containing 30 mg of Karen Zinc for 7 days.

Category

Other

2

Description

Control group: In the control group, the placebo will be similar in terms of shape and composition, with the only difference from the intervention group in the absence of the element.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Hamed Mohammadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Futohi

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Grant name

Research assistant of Tehran University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Hamed Mohammadi

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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