

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of selenium administration on complete blood count in elderly patients admitted to critical care unit

Protocol summary

Study aim

Determining the effect of selenium administration on complete blood count (CBC) in the elderly admitted to the intensive care unit

Design

A double-blind randomized clinical trial with two groups: Selenium and control group

Settings and conduct

The study will be conducted at Imam Reza and Shohada Hospital. Patients will be randomly divided into two groups of selenium, and Selin by the block method. The researchers and participants will not be aware of the groups involved.

Participants/Inclusion and exclusion criteria

Patients over 60 years admitted to the intensive care unit of Shohada and Imam Reza Hospital with an APACHE II score above 15 will be included in the study. Exclusion criteria include a history of malignancy, Renal failure, and Suppression of the immune system

Intervention groups

Selenium group will receive bolus administration of selenium (3000 µg) for 3 hours in the beginning, and then they will receive 1500 µg /day for one hour for 10 days. Patients in the control group will receive normal saline for 10 days.

Main outcome variables

Platelet amount that will be checked with complete blood count.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091012002582N23**

Registration date: **2021-05-18, 1400/02/28**

Registration timing: **prospective**

Last update: **2021-05-18, 1400/02/28**

Update count: **0**

Registration date

2021-05-18, 1400/02/28

Registrant information

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of selenium administration on complete blood count in elderly patients admitted to critical care unit

Public title

The effect of selenium administration on complete blood count in elderly patients admitted to critical care unit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients above 60 years admitted to critical care unit
APACHE II above 15

Exclusion criteria:

History of malignancy Renal failure Suppression of the immune system

Age

From **60 years** old to **100 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, the blocks (n=4) with different arrangements of A and B will be defined. Considering the different probable arrangements of A and B, blocks will be numbered from 1 to 6. To enroll the initial 4 patients into the study, one of the arrangements will be selected using the random digit table and the patients will be assigned into the A and B groups accordingly. For the next 4 patients, the arrangement pattern will be selected again and the patients will be assigned to the groups and this cycle will be repeated to achieve our intended sample size. The unpredictability of assignment and balancing the number of patients across the two groups during or at the end of the study are the main advantages of this method. Notably, the patients will be assigned into the study based on the ICU date of admission and nobody will be able to assign the patients to the specific group of interest.

Blinding (investigator's opinion)

Double blinded

Blinding description

The aim of double-blinding is the avoidance of patients and researchers from being informed about the study intervention, so enrollment of patients in groups will not be recognized. The patients will be assigned into the study based on the ICU date of admission and determined series by randomization process (based on blocks) and the researcher will not be aware of the patient's assignment in the intervention and control groups. The informed consent will be obtained from the patient's next of kin and they will thoroughly be informed about the study but they will be blind about the group in which their patient will be included.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

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Golgasht street, Tabriz, Iran

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Approval date

2021-02-22, 1399/12/04

Ethics committee reference number

IR.TBZMED.REC.1399.1076

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

Other infectious disease

ICD-10 code

B99.8

ICD-10 code description

Other infectious disease

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

platelet

Timepoint

days 1th and 10th

Method of measurement

Complete blood count

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

Red Cell Distribution Width

Timepoint

Days 1th and 10th

Method of measurement

Complete blood count

2**Description**

The ratio of neutrophils to lymphocytes

Timepoint

Days 1th and 10th

Method of measurement

Complete blood count

Intervention groups**1****Description**

Intervention group: Patients in the intervention group will receive bolus administration of IV selenium (3000 µg) (produced by Biosyn company, Germany) during 3 hours at the beginning, and then they will receive 1500 µg /day during one hour for 10 days

Category

Treatment - Drugs

2**Description**

Control group: Patients in control group will receive normal saline as the same volume and speed for 10 days.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohada hospital, ICU

Full name of responsible person

Ata Mahmoodpoor

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2**Recruitment center****Name of recruitment center**

General ICU of Imam Reza hospital

Full name of responsible person

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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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

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Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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

No more 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