Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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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Iran (Islamic Republic of)

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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

Street address
Golgasht street, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

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 bollus administraion 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

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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