Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of high dose of selenium in mortality of patient with severe sepsis

Protocol summary

Summary

This study is a randomized controlled clinical trial that include 51 adult patients suffering from severe sepsis with Acute Physiology and Chronic Health Evaluation II score (APACHE II) above 12, admitted to intensive Care Unit (ICU) of Sina hospital. Patients will be randomly divided into 2 groups: one group will receive standard treatment for sepsis according to SSC, another group will receive standard treatment for sepsis plus high dose of Selenium. All patients will have CV line. Biomarkers will be measured in the following days 1, 3, 5, 7, 10, and 14. On the first day of the study, the patients in Selenium group will receive 2000 micrograms Selenium as bolus dose during an hour followed by 1500 micrograms Selenium in 50 milliliter normal saline as 24-hour infusions for 14 days. We will follow the patients' mortality from all causes up to 28 days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212082887N4**
Registration date: **2014-08-29, 1393/06/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-08-29, 1393/06/07

Registrant information

Name

mojtaba mojtahedzadeh

Name of organization / entity

pharmacy school of tehran university of medical science

Country

Iran (Islamic Republic of)

Phone

02166735168-02164122209

Email address

mojtahed@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2012-02-01, 1390/11/12

Expected recruitment end date

2014-02-01, 1392/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of high dose of selenium in mortality of patient with severe sepsis

Public title

The effects of high dose of selenium in the treatment of patient with severe sepsis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patient with suspected or documented diagnosis of infection with at least one of these: White blood cell (WBC) in sterile regions, Perforated viscera; Radiologic evidence of pneumonia and infected sputum; High risk infection such as Cholangitis; and at least three of the following: Body temperature above 38 degrees Celsius or under 36; Heart rate greater than 90 beat per minute without consuming any medication, Respiratory rate more than 20 per minute or arterial pressure of

carbon dioxide less than 32 millimeter of mercury with mechanical ventilation; White blood cells more than 12000 or less than 1000; more than 10 percent band Neutrophils. Exclusion criteria: more than 24 hours of diagnosis of sever sepsis; high probability death due to a nonspecific cause (renal insufficiency, hepatic encephalopathy, etc) within the first 28 days; pregnancy or lactating; Age less than 16 years; dissatisfaction of patient or his family to enter the study; patients with Cancer

Age
From **17 years** old to **90 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **51**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Before the beginning of the study by software the numbers of patients are randomly divided into 2 groups. With the arrival of each patient the cards are open for patient that the groups of patient are diagnosed.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research center of Science Tehran University of Medical sciences

Street address
Old building's School of Pharmacy, Tehran University of Medical Sciences

City
Tehran

Postal code
1417614411

Approval date
2011-06-19, 1390/03/29

Ethics committee reference number
(1-1: 90-3-29)

Health conditions studied

1

Description of health condition studied
Severe sepsis

ICD-10 code
R65.1

ICD-10 code description
Systemic Inflammatory Response Syndrome of infectious origin with organ failure Severe sepsis

Primary outcomes

1

Description
Mortality

Timepoint
Mortality within 28 days of after diagnosis with severe sepsis

Method of measurement
Counting the number of patient died

2

Description
Length of ICU stay

Timepoint
Number of bed days in ICU since entry into the research

Method of measurement
Registration for beding in ICU

Secondary outcomes

1

Description
Level of Super Oxide Dismutase

Timepoint
Base line and day 3, 7, 10, 14 after prescription.

Method of measurement
measuring enzyme concentration in the blood

2

Description
MMP (Matrix Metalloproteinase)

Timepoint
Baseline and day 3, 7, 10, 14 after treatment with selenium

Method of measurement
measuring the enzyme concentration in the blood

3

Description
PAF (Platelet-activating factor)

Timepoint
Baseline and day 3, 7, 10, 14 days after treatments with selenium.

Method of measurement

measuring the concentration of PAF in the blood

4

Description
Total anti oxidant power
Timepoint
Baseline and day 3, 7, 10, 14 after treatments with selenium.
Method of measurement
measuring Anti-oxidant power concentration in the blood

5

Description
Interleukin 1
Timepoint
Baseline and day 3, 7, 10, 14 after treatments with selenium
Method of measurement
measuring IL-1 concentration in the blood

6

Description
TGF (Transforming Growth Factor)
Timepoint
Baseline and day 3, 7, 10, 14 after treatment with selenium.
Method of measurement
measuring TGF concentration in the blood

7

Description
SOFA Score (Simplified Acute Physiology Score)
Timepoint
Baseline and day 3, 7, 10, 14 after treatments with selenium
Method of measurement
Calculation

8

Description
APACHI II Score (Acute Physiology and Chronic Health Evaluation II)
Timepoint
Baseline and day 3, 7, 10, 14 after treatment with selenium
Method of measurement
Calculation

9

Description
NGAL (Neutrophil Gelatinase Associated Lipocalin)
Timepoint
Baseline and day 3, 7, 10, 14 after treatment with selenium
Method of measurement
measuring NGAL concentration in the blood

Intervention groups

1

Description
One the first day study, begining 2000 microgram selenium boluses (in 1 hour) then 1500 microgram selenium 24 hour infusion for 14 days in 50 milliliter sodium chloride solution.
Category
Treatment - Drugs

2

Description
The standard treatment for sepsis without prescription selenium
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Aarezoo Ahmadi
Street address
Sina Hospital, Emam Khomeini Street, Hasan abad Square, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Ms.Saidi
Street address
Tehran University of Medical Sciences- Vice chancellor for research- Keshavarz blvd corner- Ghods street-Enghelab avenue
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Sina Hospital

Full name of responsible person

Arezoo Ahmadi

Position

Critical Care Fellowship

Other areas of specialty/work

Street address

Sina Hospital, Emam Khomeini Street, Hasan abad Square, Tehran

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+98 21 6634 8500

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aarezoo24@gmail.com

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sina Hospital

Full name of responsible person

Arezoo Ahmadi

Position

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Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Sina Hospital

Full name of responsible person

Arezoo Ahmadi

Position

Critical Care Fellowship

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Phone

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Fax

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty