

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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, beginning 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

Aarezo 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

Tehran
Postal code
Phone
+98 21 6634 8500
Fax
Email
Aarezoo24@gmail.com
Web page address

Person responsible for general inquiries

Contact

Name of organization / entity
Sina Hospital
Full name of responsible person
Aarezoo Ahmadi
Position
Critical Care Fellowship
Other areas of specialty/work
Street address
Sina Hospital, Emam Khomeini Street, Hasan abad
Square, Tehran
City
Tehran
Postal code
Phone
+98 21 6634 8500
Fax
Email
aarezoo24@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Sina Hospital
Full name of responsible person
Aarezoo Ahmadi
Position
Critical Care Fellowship
Other areas of specialty/work
Street address
Sina Hospital, Emam Khomeini Street, Hasan abad
Square, Tehran
City

Person responsible for updating data

Contact

Name of organization / entity
Sina Hospital
Full name of responsible person
Aarezoo Ahmadi
Position
Critical Care Fellowship
Other areas of specialty/work
Street address
Sina Hospital, Emam Khomeini Street, Hasan abad
Square, Tehran
City
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00
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Email
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