Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

The effect of intravenous selenium on stress oxidative in ARDS patients in intensive care units

Protocol summary

Summary

Objectives: 1- Determining the effects of intravenous Selenium on reducing mechanical ventilation period in ARDS patients; 2-Determining the effects of intravenous Selenium on the duration of hospitalization of ARDS patients in intensive care unit (ICU); 3- Determining the effects of intravenous Selenium on discontinuing treatment with vasopressors in ARDS patients in ICU; 4-Determining the effects of intravenous Selenium on end-organ damage parameters (SOFA) in ARDS patients in ICU Design: study groups: This study will be conducted as a randomized clinical trial.Patients will be divided into two groups of treatment with intravenous selenium and placebo; sample size: 40; Blinding: not-blinded; randomization: patients will be divided into two groups, randomly, using Gravtron 2.0 software; Centers: it was a two-centered study, conducted in Shohada and Imam Reza hospitals; Phase: Not Applicable Setting and conduct: Group A patients will receive intravenous Selenium for 10 days, and Group B patients will receive the same amount of placebo. From all patients, on days 0, 7, and 14 blood samples will be obtained to evaluate the antioxidant status, using glutathione peroxidase kits (TRAP and FRAP). Demographic characteristics, duration of mechanical ventilation, length of hospitalization in ICU, duration of receiving vasopressors, mechanical Indices, Arterial blood gas parameters, SOFA (Sequential Organ Failure Assessment), causes of ICU hospitalization, mortality and receiving fluids will be recorded. Major inclusion criteria: patients above 18 years; asymmetric and diffused involvemnet of lungs in chest X-ray; lung involvement less than a week; proportion of arterial oxygen pressure (Pao2) to Fio2 more than 200; Exclusion criteria: hypersensitivity to Selenium; pregnancy and lactation; renal failure Intervention: Intravenous Selenium Primary outcome measures: Ventilation free days, oxidative stress status (based on Glutathione peroxidase) Secondary outcome measures: Vasopressor free days

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706172582N17**
Registration date: **2017-09-12, 1396/06/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-09-12, 1396/06/21

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

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2017-10-01, 1396/07/09

Expected recruitment end date

2018-06-01, 1397/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of intravenous selenium on stress oxidative in ARDS patients in intensive care units

Public title
The effect of intravenous selenium on stress oxidative in Acute Respiratory Distress Syndrome (ARDS) patients in intensive care units

Purpose
Treatment

Inclusion/Exclusion criteria
Major inclusion criteria: patients above 18 years; asymmetric and diffused involvemnet of lungs in chest X-ray; lung involvement less than a week; proportion of arterial oxygen pressure (Pao2) to Fio2 more than 200; Exclusion criteria: hypersensitivity to Selenium; pregnancy and lactation; renal failure

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

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
Tabriz University of Medical Sciences, Golgasht street

City
Tabriz

Postal code

Approval date
2017-07-03, 1396/04/12

Ethics committee reference number
IR.TBZMED.REC.1396.277

Health conditions studied

1

Description of health condition studied
Acute respiratory distress syndrome

ICD-10 code
j80

ICD-10 code description
Adult respiratory distress syndrome

Primary outcomes

1

Description
oxidative stress status(gluthatione peroxidase)

Timepoint
One day before the intervention. Seven days after intervention. Fourteen days after the intervention

Method of measurement
using FRAP and TRAP kits

2

Description
ventilation free days

Timepoint
number of days that patients do not require mechanical ventilation, within the 14 days of study period

Method of measurement
with counting the ventilation free days and recording them in forms

Secondary outcomes

1

Description
vasopressor free days

Timepoint
number of days that patients do not require vasopressor administration, within the 14 days of study period

Method of measurement
with counting vasopressor free days and recording them in forms

Intervention groups

1

Description
intervention group 1: these patients will be administered with 4 mg of intravenous selenase (produced by Biosyn company, Germany). Then, for 3 days the will receive 1mg/12h then for the last 10 days they will be injected by 1mg/day of it.

Category
Treatment - Drugs

2

Description
Control group 1: they will receive placebo with the exact same doses.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Hospital
Full name of responsible person
Dr Ata Mahmoodpoor
Street address
Golshahr street, El-goli freeway
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2

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Dr Ata Mahmoodpoor
Street address
Golgasht street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Alireza Ostadrahimi
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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
Vice chancellor for research, Tabriz 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
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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