

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 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 involvement 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

Name

Ata Mahmoodpoor

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 involvement 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 (glutathione 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 they 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

City

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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

City

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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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Tabriz University of Medical Sciences, Golgasht street

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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

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Position

sub-specialty fellowship of intensive care medicine

Other areas of specialty/work

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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