

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Comparison of the average superoxide dismutase enzyme in the groups receiving selenium and n-acethylcysteine antioxidants in severe trauma patients admitted to an intensive care unit

#### Protocol summary

##### Study aim

Comparison of the average superoxide dismutase enzyme in the groups receiving selenium and n-acethylcysteine antioxidants in severe trauma patients admitted in an intensive care unit.

##### Design

Randomised, single blind Clinical trial on severe trauma patients. After determination of the sample size by blocked randomization method patients divided into three groups of twenty patients (2 patients in the case group 1 and 2 patients in case group 2 and 2 patients in control group)

##### Settings and conduct

this research is a single blind clinical trial on cases with severe trauma in admitted in the ICU of kerman Bahonar hospital in the year 1398. Patients were randomly divided into three groups according to age and sex. After explaining to the patients family about the research and taking the written consent the patients will be entered in to the research. protocol to receive medication: first group will receive N-acetyl cystine as the protocol. also second group will under go treatment with Selenium as per the protocol and the control group will receive placebo. on the third day we take 5cc serum sample from the participant (in the test tube without anti-coagulant ) and we analyze the supra oxidant activity based on the ELISA method using Pajohan Teb kit.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria age 18 years old and up .Exclusion criteria incomplete demographic factor. underlying disease.organ failaure .drug sensitivity.

##### Intervention groups

patients are divided into 3 groups first group will go under N-acetyl cysteine treatment as per the protocol, second group will under go treatment by selenium as per the protocol . control group will receive placebo. The test will be takekn3 days later after first dose

##### Main outcome variables

superoxide desmotaze: hospitalization period :level of concsiousness :organ failure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201109049317N1**

Registration date: **2021-05-03, 1400/02/13**

Registration timing: **retrospective**

Last update: **2021-05-03, 1400/02/13**

Update count: **0**

##### Registration date

2021-05-03, 1400/02/13

##### Registrant information

##### Name

Leili Asadabadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3211 8067

##### Email address

asadabadi.l@vums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-05, 1398/05/14

##### Expected recruitment end date

2019-11-05, 1398/08/14

##### Actual recruitment start date

2019-11-11, 1398/08/20

**Actual recruitment end date**

2019-11-11, 1398/08/20

**Trial completion date**

2020-02-10, 1398/11/21

**Scientific title**

Comparison of the average superoxide dismutase enzyme in the groups receiving selenium and n-acetylcysteine antioxidants in severe trauma patients admitted to an intensive care unit

**Public title**

Effect of selenium and n-acetylcysteine antioxidants on superoxide dismutase enzyme.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age older than 18 year Severe trauma patients need to admit in an Intensive Care Unit

**Exclusion criteria:**

Incomplete demographic information Preexisting conditions Sepsis and organ failure Drug sensitivity

**Age**

From **18 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After determination of the sample size by block randomization method patients divided into three groups of twenty patients (2 patients in the case group 1 and 2 patients in case group 2 and 2 patients in control group) Based on the time of patient entrance, patients divided into groups consist of 6 patients then accidentally each group divided into 3 sub group. To do randomization all ABC cases (AABBCC, ABCABC....) are considered. Then we put them on the envelopes and we arrange 6 groups of envelopes, in each group, the group name was repeated 2 times. After evaluation of inclusion and exclusion criteria the selected patient or his family choose the pocket and the group. To blind patients and researchers, the groups are placed in an envelope in the form of ABC. This process repeated for each patient to obtain the final sample size.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

As the color and the shape of the drugs are the same, The patients did not know which drugs they are getting.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

**Street address**

Emam Highway. Afzalipour Hospital

**City**

kerman

**Province**

Kerman

**Postal code**

7616913911

**Approval date**

2019-08-13, 1398/05/22

**Ethics committee reference number**

IR.KMU.AH.REC.1398.069

**Health conditions studied****1****Description of health condition studied**

Sever Trauma

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Superoxide dismutase

**Timepoint**

3 days after drug infusion

**Method of measurement**

Superoxide Dismutase Assay Kit

**Secondary outcomes****1****Description**

Organ function

**Timepoint**

3 days after drug infusion

**Method of measurement**

APACHI 2

**2**

**Description**

level of consciousness

**Timepoint**

3days after drug infusion

**Method of measurement**

Glasco Coma Scale

**3**

**Description**

Duration of hospitalization

**Timepoint**

Days of hospitalization after drug infusion

**Method of measurement**

Days of hospitalization

**Intervention groups**

**1**

**Description**

Intervention group: Selanase vial 50 mcg in 10 cc.FIRST.Receive selenium in first day 1000 mcg over 24 hours.second day 400 mcg over24 hours.third day 200 mcg over24 hours.

**Category**

Treatment - Drugs

**2**

**Description**

Control group:Recieve Placebo=2fi00 cc normal saline over 24 hours for 3 days.

**Category**

Placebo

**3**

**Description**

Intervention group: Second.Recive N.Acetylcystein20% vial=first day 300mg per kilogram over 24 hours.second day 150mg per kilogram over 24 hours.third day 75 mg per kilogram over 24 hours.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid bahonar hospital

**Full name of responsible person**

Farhad mazidi

**Street address**

Qarany st

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

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**Web page address**

**Grant name**

-

**Grant code / Reference number**

-

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kerman 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**

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Leili Asadabadi

**Position**

Assisstant Professor

**Latest degree**

Specialist  
**Other areas of specialty/work**  
Emergency Medicine  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

Information will be available after publishing.

### When the data will become available and for how long

6 to 12 months

### To whom data/document is available

All of researcher

### Under which criteria data/document could be used

Person who research on patients admitted in intensive care units.

### From where data/document is obtainable

Validated scientific journals

### What processes are involved for a request to access data/document

Search in valid article

### Comments