

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Evaluation of the effect of high doses of selenium on oxidative stress status and inflammatory factors in post gastrointestinal surgery children in intensive care unit

#### Protocol summary

##### Study aim

Determination of the effect of high doses of selenium on oxidative stress status and inflammatory factors in post gastrointestinal surgery children in intensive care unit

##### Design

Randomized parallel group clinical trial Single blinded  
Method of randomization : block Unit of randomization : individual Randomization strata in stratified randomization: age (>/< 1 year) and surgery (upper/lower GI) Tools used in randomization: table of random numbers Allocation concealment will carried out Target sample size: 70

##### Settings and conduct

Blinding: participants, nurses, Data analyser supplement and placebo will be similar in volume and shape.

##### Participants/Inclusion and exclusion criteria

Patients undergoing major gastrointestinal surgery at the Akbar Hospital of Mashhad and admitted to the intensive care unit due to medical indications

##### Intervention groups

Intervention group: Selenium supplementation will continue to be given at a dose of 20 µg / kg / d for 10 days or until discharge from the intensive care unit or death. High-dose selenium content will be injected intravenously 20 cc of dextrose 5% in 60 minutes.  
Control group: The placebo(serum: dextrose 5% ) with the same volume and shape as the control group will be administered, for 10 days or until discharge from the intensive care unit or death.

##### Main outcome variables

Pro-oxidant- Antioxidant Balance (PAB) status,  
Inflammatory factors

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190122042449N1**

Registration date: **2019-01-27, 1397/11/07**

Registration timing: **prospective**

Last update: **2019-01-27, 1397/11/07**

Update count: **0**

##### Registration date

2019-01-27, 1397/11/07

##### Registrant information

###### Name

Fatemeh Roudi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3800 2423

###### Email address

roudif951@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-06, 1397/11/17

##### Expected recruitment end date

2019-09-22, 1398/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of high doses of selenium on oxidative stress status and inflammatory factors in post

gastrointestinal surgery children in intensive care unit

#### Public title

effect of selenium on oxidative stress status and inflammatory factors in post gastrointestinal surgery children

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

0-10 years old patients undergoing major gastrointestinal surgery at the Akbar Hospital of Mashhad Admission to the intensive care unit due to medical indications Filling out the informed consent form by a parent or legal guardian Stability of hemodynamic and metabolic status in the first 24 to 48 hours

##### Exclusion criteria:

Patients who are not allowed to start a nutrition support care for them within the first 24-48 hours Diagnosed autoimmune disorders Diagnosed cancers Severe sepsis at the admission time History of chemotherapy and radiotherapy in the past month Diagnosed renal failure Diagnosed severe hepatic failure Severe and active bleeding A known case of human immunodeficiency virus Preterm neonates

#### Age

From **1 day** old to **10 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Data analyser

#### Sample size

Target sample size: **70**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Method of randomization : block Unit of randomization : individual Randomization strata in stratified randomization: age (>/< 1 year) and surgery (upper/ lower GI) Tools used in randomization: table of random numbers Allocation concealment will carried out

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

With the exception of a pharmacist,corresponding physician and investigator the supplement/ placebo assignment will be concealed from the patients, nursing system, data analyser and safety monitoring board throughout the study.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Science

##### Street address

Campus of University (Paradise Daneshgah), Azadi Square

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91779-48564

#### Approval date

2018-12-18, 1397/09/27

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.553

## Health conditions studied

### 1

#### Description of health condition studied

Digestive System Surgical Procedures

#### ICD-10 code

K56.60

#### ICD-10 code description

Unspecified intestinal obstruction

### 2

#### Description of health condition studied

selenium deficiency

#### ICD-10 code

E64.8

#### ICD-10 code description

Sequelae of other nutritional deficiencies

### 3

#### Description of health condition studied

Congenital diaphragmatic hernia

#### ICD-10 code

Q79.0

#### ICD-10 code description

Congenital diaphragmatic hernia

### 4

#### Description of health condition studied

Acute abdomen

#### ICD-10 code

R10.0

#### ICD-10 code description

Acute abdomen

## 5

### **Description of health condition studied**

Congenital malformations of esophagus

### **ICD-10 code**

Q39

### **ICD-10 code description**

Congenital malformations of esophagus

## 6

### **Description of health condition studied**

Other specified congenital malformations of upper alimentary tract

### **ICD-10 code**

Q40

### **ICD-10 code description**

Other congenital malformations of upper alimentary tract

## 7

### **Description of health condition studied**

Congenital disorders of small intestine

### **ICD-10 code**

Q41

### **ICD-10 code description**

Congenital absence, atresia and stenosis of small intestine

## 8

### **Description of health condition studied**

Congenital disorders of large intestine

### **ICD-10 code**

Q42

### **ICD-10 code description**

Congenital absence, atresia and stenosis of large intestine

## 9

### **Description of health condition studied**

Congenital malformations of gallbladder, bile ducts and liver

### **ICD-10 code**

Q44

### **ICD-10 code description**

Congenital malformations of gallbladder, bile ducts and liver

## **Primary outcomes**

### 1

#### **Description**

Pro-oxidant- Antioxidant Balance (PAB) status

#### **Timepoint**

before intervention and after 10 days

#### **Method of measurement**

Pro-oxidant- Antioxidant Balance (PAB) assay

## 2

#### **Description**

inflammatory factors

#### **Timepoint**

before intervention and after 10 days

#### **Method of measurement**

Interleukin 1 beta: ELISA, high-sensitivity C-reactive protein (hs-CRP) test: Immunoturbidimetry

## **Secondary outcomes**

### 1

#### **Description**

Serum and urine selenium Level

#### **Timepoint**

before intervention and 1, 10 days after intervention

#### **Method of measurement**

atomic absorption

### 2

#### **Description**

Serum Glutathione peroxidase level

#### **Timepoint**

before intervention and 1, 10 days after intervention

#### **Method of measurement**

ELISA

## **Intervention groups**

### 1

#### **Description**

Intervention group: Selenium supplementation will continue to be given at a dose of 20 µg / kg / d for 10 days or until discharge from the intensive care unit or death. High-dose selenium content will be injected intravenously 20 cc of dextrose 5% in 60 minutes. Injectable selenium in sodium selenite form with a concentration of 50 µg / ml by the Pharmacy school of Mashhad University of Medical Sciences will be used.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: The placebo (serum: dextrose 5%) with the same volume and shape as the intervention group, for 10 days or until discharge from the intensive care unit or death.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

**Name of recruitment center**

Akbar hospital

**Full name of responsible person**

Dr. Gholamreza Khademi

**Street address**

Shahid Kaveh boulevard

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91779-48564

**Phone**

+98 51 3871 3801

**Email**

KhademiGH@mums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Deputy of Research and Technology of the University,  
Qoreishi Center, Daneshgah street.

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

13131 - 99137

**Phone**

+98 51 3841 1538

**Email**

tafaghodim@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fatemeh Roudi

**Position**

PhD student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Nutrition

**Street address**

Mashhad University of Medical Sciences (MUMS)  
Campus of University (Paradise Daneshgah), Azadi  
Square

**City**

Mashhad

**Province**

Razavi Khorasan

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**Phone**

+98 51 3800 2423

**Fax**

**Email**

roudif951@mums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fatemeh Roudi

**Position**

PhD student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fatemeh Roudi

**Position**

PhD student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Phone**

+98 51 3800 2423

**Fax**

**Email**

roudif951@mums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

The non-identifiable individual participant data collected in this study will be shared. Also, The protocol, results, and statistical analysis of the current study will be published in the relevant articles.

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

The non-identifiable individual participant data will become available after the publication of the relevant articles.

**To whom data/document is available**

they will be available for people working in academic institutions and people working in businesses can also apply to receive it.

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

The non-identifiable individual participant data can only be used for research.

**From where data/document is obtainable**

The non-identifiable individual participant data will be obtainable by sending an e-mail to Dr. Mohsen Nematy. ( e-mail address: NematyM@mums.ac.ir)

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

Other researchers in academic institutions can send their request by e-mail to Dr. Mohsen Nematy. The data will be sent to them after consulting and approving the research team.

**Comments**