

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Effect of selenium supplementation on glutathione peroxidase enzyme activity in patients with chronic kidney disease

#### Protocol summary

##### Summary

This study is a randomized, clinical trial. Study group include patients with chronic kidney disease with age between 20-65 years that visited in Tooba Nephrology clinic. These patients divide into 3 subgroups (with 15 patients in each subgroup) as creatinine clearance. 1) Subgroup with creatinine clearance between 60-89 ml/min (mild CKD). 2) Subgroup with creatinine clearance between 30-59 ml/min (moderate CKD). 3) Subgroup with creatinine clearance less than 30 ml/min (severe CKD). First, selenium plasma level and glutathione peroxidase enzyme activity are measured in all patients as baseline. Then, a 200 microgram selenium tablet (Nature Made product, made in USA) is administered daily to each patient in all 3 subgroups in fasting state. After 3 months, selenium plasma level and glutathione peroxidase enzyme activity are measured in all patients and will be compared with baseline data by statistical analysis.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201305318501N2**

Registration date: **2013-06-29, 1392/04/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-06-29, 1392/04/08

##### Registrant information

###### Name

Omid Sedighi

###### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1325 7230

##### Email address

osedighi@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mazandaran University of Medical Sciences

##### Expected recruitment start date

2012-12-21, 1391/10/01

##### Expected recruitment end date

2013-05-22, 1392/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of selenium supplementation on glutathione peroxidase enzyme activity in patients with chronic kidney disease

##### Public title

Effect of selenium supplementation on glutathione peroxidase enzyme activity in patients with chronic kidney disease

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1) Patient with chronic kidney disease for  $\geq 3$  month 2) patients  $\geq 20$  years and  $< 65$  years 3) Plasma albumin level  $4$  g/dl Exclusion criteria: 1) Acute infection 2) Recent acute myocardial infarction during 6 week ago 3) Recent consumption of antioxidant drugs (for example vitamins A, E, C) 4) Active smoking 5) History of new or old cancer 6) Liver failure

**Age**

From **20 years** old to **65 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

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

empty

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

Mazandaran University of Medical Sciences

**Street address**

Department of Research and Technology, Moallem Square

**City**

Sari

**Postal code****Approval date**

2012-12-19, 1391/09/29

**Ethics committee reference number**

91-154

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

Chronic kidney disease

**ICD-10 code**

N18

**ICD-10 code description**

Chronic kidney disease

**Primary outcomes****1****Description**

glutathione peroxidase enzyme activity

**Timepoint**

Before study, Three months after drug supplementation

**Method of measurement**

ELISA (Kit made by UK)

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

selenium plasma level

**Timepoint**

Before study, Three months after drug supplementation

**Method of measurement**

Electrothermal atomic absorption spectrometry(ETAAS)

**Intervention groups****1****Description**

selenium tablet (Nature Made product, made in USA) 200 microgram/day for 3 months to all patients

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Tooba medical clinic center

**Full name of responsible person**

Omid Sedighi

**Street address**

Tooba medical clinic center- Khazar Bolvard

**City**

Sari

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Ahmad Ali Enayati

**Street address**

Department of Research and Technology, Moalem Square

**City**

Sari

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Omid Sedighi

**Position**

Nephrologist\Faculty Member

**Other areas of specialty/work****Street address**

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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*