Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Nephrlogy 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 (sever 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 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)

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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 ≥ 3 month 2) patients≥ 20 years and<65 years3) 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 vitamine 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 absorbtion 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
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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
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

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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