# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Evaluation of the effect of oral selenium administration on tremor reduction of Parkinsonians

## Protocol summary

**Summary**

The aim of this study is to investigate the effect of selenium on parkinsonians' tremor treatment. In total, 26 patients with parkinson disease will be enrolled the clinical trial. The trial is based on 2 periods of two months drug prescription with 2weeks drug free between prescriptions. Placebo and 200 µg selenium will be prescribed in order in each separated 2 months. Primary outcome of this study is tremor index based on Tremor Research Group Rating Scale. Severity of disease and side effects of the drug will be measured at the end of each month drug prescription. At least 2 declines in scale will be considered as appropriate response.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201101155612N1**
Registration date: **2014-01-09, 1392/10/19**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2014-01-09, 1392/10/19

**Registrant information**

**Name**
Ali Mellat Ardekani
**Name of organization / entity**
Yazd University of Medical Siences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 35 1822 4001
**Email address**
ali_mellat@ssu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Yazd University of Medical Sciences

**Expected recruitment start date**

2014-01-21, 1392/11/01

**Expected recruitment end date**

2014-04-21, 1393/02/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of oral selenium administration on tremor reduction of Parkinsonians

**Public title**

Evaluation of the effect of oral selenium administration on tremor reduction of Parkinsonians

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusions: Idiopathic Parkinson disease; Age between 40 and 60 years; 6 months after diagnosis the disease; stage 2.5 or less based on MODIFIED HOEHN AND YAHR STAGING 5 ; Apparent or troublesome tremor
Exclusions:Other disease induses tremor; out of age range between 40 to 60 years

**Age**

From **40 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **26**

**Randomization (investigator's opinion)**
N/A

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Yazd University of Medical Sciences

**Street address**
Bahonar Sq. Yazd. Iran

**City**
Yazd

**Postal code**

**Approval date**
2013-12-18, 1392/09/27

**Ethics committee reference number**
17/1/186945/ب

## Health conditions studied

### 1

**Description of health condition studied**
Tremor

**ICD-10 code**
G20

**ICD-10 code description**
Parkinson disease

## Primary outcomes

### 1

**Description**
Tremor rate

**Timepoint**
At beginning, End of 2 months

**Method of measurement**
Based on exam,Observation and Physical exam, indices (0-16) will be measured every 2 months (before and after treatment)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
First intervention: one capsule (placebo or 200 mg selenium) daily for 2 months will be prescribed to 26 patients and indices will be measured at first and the end. Second intervention: after 2 week's washout period, one capsule (placebo or 200 mg selenium) daily for 2 months will be prescribed to 26 patients and indices will be measured at first and the end.

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Khatamolanbia Clinic

**Full name of responsible person**
Ali Mellat Ardekani

**Street address**
Taaleghani Bl. Yazd

**City**
Yazd

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Yazd University of Medical Sciences

**Full name of responsible person**
Ezoddini Fatemeh

**Street address**
Bahonar Sq, Yazd, Iran

**City**
Yazd

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Yazd 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**
Yazd University of Medical Sciences
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**Position**
Neurologist, Assistant professor
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Yazd University of Medical Sciences
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Neurologist, Assistant professor
**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*