

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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 Sciences

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 induces 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
Khatamolania 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

Full name of responsible person

Ali Mellat Ardekani

Position

Neurologist, Assistant professor

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

Neurology Department, Shahid Sadoughi Hospital,
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Person responsible for updating data

Contact

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Full name of responsible person

Ali Mellat Ardekani

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Person responsible for scientific inquiries

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Shahid Sadoughi Hospital, Yazd University of Medical
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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