Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Iran (Islamic Republic of)
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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

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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
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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