Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of treatment with zinc supplements on depression and neurologic symptoms in patients with multiple sclerosis

Protocol summary

Summary

Goal: to study the effect of treatment with zinc supplements on depression and neurologic symptoms in patients with multiple sclerosis. A double blind-placebo controlled study. Study population: MS patients in city of Sanandaj. Sample size: 25 patients in each group. Inclusion criteria: having major depressive disorder based on the beck questionnaire with a score of 19; MS patients according to clinical and paraclinical findings. Exclusion criteria: having a personality disorder; serious disease including renal failure, hepatic insufficiency, ischemic heart disease, cancer, endocrine and metabolic disease. Among patients with definite diagnosis of multiple sclerosis, 50 patients (with score above 19 by Using the Beck Depression Inventory which includes 21 questions) are selected. They are divided into two equal groups. These patients are examined in terms of vision problems (Nystagmus), muscle strength and balance disorder (Ataxia). Patients would be on the treatment of MS based on their own treatment plan which they got before the study. Intervention group receive zinc sulfate (220 mg containing 50 mg zinc, Alhavi pharmaceutical co .Iran) daily for 12 weeks. Control group receive placebo. After the end of treatment period, patients will be evaluated for depression and neurological symptoms again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012081010550N1**
Registration date: **2012-11-06, 1391/08/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-11-06, 1391/08/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

University of Medical Sciences, Sanandaj

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2012-08-20, 1391/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of treatment with zinc supplements on depression and neurologic symptoms in patients with multiple sclerosis

Public title

Effect of zinc on the treatment of depression and multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having major depressive disorder

based on the beck questionnaire with a score of 19; MS patients according to clinical and paraclinical findings. Exclusion criteria: having a personality disorder; Education below than elementary fifth; symptoms of a psychotic disorder; other neurological disorders except MS; Serious disease including renal failure, hepatic insufficiency, ischemic heart disease, cancer, endocrine and metabolic diseases based on clinical records.

Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kurdistan University of Medical Sciences
Street address
Pasdaran Avenue, Kurdestan University of Medical sciences, Vice-chancellery for Medical Information and Research Affairs
City
Sanandaj
Postal code
P.O.Box 1344666177
Approval date
2012-07-15, 1391/04/25
Ethics committee reference number
14/13312

Health conditions studied

1

Description of health condition studied
depression
ICD-10 code
F33
ICD-10 code description
Recurrent depressive disorder

2

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
muscle strength
Timepoint
baseline the study and after three months
Method of measurement
scoring 0-5

2

Description
balance
Timepoint
baseline the study and after three months
Method of measurement
examination (Romberg test,Tandem gate test)

3

Description
Depression
Timepoint
baseline the study and after three months
Method of measurement
Beck Depression Inventory

4

Description
nystagmus
Timepoint
baseline the study and after three months
Method of measurement
examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group receive zinc sulfate (220 mg containing 50 mg zinc, Alhavi pharmaceutical co .Iran) daily for 12 weeks.

Category
Treatment - Drugs

2

Description
Control group receive placebo.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
MS Society of Kurdistan
Full name of responsible person
Street address
Chahar Bagh Avenue below Hariri Mosque
City
Sanandaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Ataollah Haydari
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Grant name
بند 3 صورتجلسه شورا به شماره 14/8747 در تاریخ 1391/3/21
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kurdistan 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