

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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, Alvahi 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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Soheila Salari

Name of organization / entity

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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, Kurdistan 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**

Kurdistan University of Medical Sciences

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**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