

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of zinc supplementation on depression and certain inflammatory cytokines depression in patients with major

Protocol summary

Summary

Major depression is a common illness in the world and the various treatments used to treat depression or reduce its symptoms. Some studies have shown that zinc is concentrated in specific areas of brain and dietary zinc deficiency can influence homeostasis of zinc in brain and may predispose the individual to psychiatric disorders including depression. In this study, we will examine the effect of zinc supplementation on depression status. Patients with major depression referred to a psychiatrist who meet the inclusion criteria if willing are invited to participate in the study. Patients will randomly divided into two groups. In the first group, patients received a zinc sulfate capsule containing 25 milligrams of zinc plus previous medication and in the second group, a placebo plus each patient's previous medication is given for 12 weeks. After 6 and 12 weeks, in both groups depression will be examined based on the Beck and Hamilton questionnaire. In the beginning and at the end of study, a fasting blood sample (5 mL) is taken from all patients and plasma concentrations of zinc, Tumor Necrosis Factor- α , Interleukin-6 and Brain-derived Nerve Factor is determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110187836N1**
Registration date: **2011-11-06, 1390/08/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-11-06, 1390/08/15

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Neuroscience Research Center, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2012-01-21, 1390/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of zinc supplementation on depression and certain inflammatory cytokines depression in patients with major

Public title

Effect of zinc supplementation in major depression

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: - A diagnosis of major depressive disorder - Have no current medical illness (diabetes, cancer, cardiovascular, inflammatory, liver or renal diseases) - No antepartum or postpartum depression - Current treatment with medication except for depressive

disorder - Current use of multivitamin-mineral supplement Exclusion criteria: - pregnancy or lactation - any change in medication - A diagnosis of a new medical illness during study

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

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

Neuroscience Research Center

Street address

Shahid Beheshti University of Medical Sciences

City

Tehran

Postal code

Approval date

2012-03-04, 1390/12/14

Ethics committee reference number

t/1/044

Health conditions studied

1

Description of health condition studied

Major Depression

ICD-10 code

F32.2

ICD-10 code description

Severe depressive episode without psychotic symptoms

Primary outcomes

1

Description

Depression

Timepoint

at the begining, after 6 and 12 weeks of supplementation

Method of measurement

Hamilton and Beck Depression Rating Scale

Secondary outcomes

1

Description

Plasma concentration of brain-derived growth factor

Timepoint

Before and after 12 weeks of treatment

Method of measurement

Biochemical assay

2

Description

Plasma concentration of Tumor Necrosis Factor-a

Timepoint

Before and after 12 weeks of treatment

Method of measurement

Biochemical assay

3

Description

Plasma concentration of Interleukin-6

Timepoint

Before and after 12 weeks of treatment

Method of measurement

Biochemical assay

Intervention groups

1

Description

Taking a Zinc sulfate capsule, 25 mg once a day for 12 weeks (intervention)

Category

Treatment - Drugs

2

Description

Taking a placebo capsule once a day for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hosein Hospital

Full name of responsible person
Street address
City
Tehran

Web page address

Person responsible for scientific inquiries

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Department of Clinical Nutrition and Diet therapy,
Faculty of Nutrition Sciences and Food Technology
Full name of responsible person
Dr. M. Sabetkasaei
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Neuroscience Research Center, Shahid Beheshti
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Department of Clinical Nutrition and Diet therapy,
Faculty of Nutrition Sciences and Food Technology

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