Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Effect of vitamin D supplementation on depression severity, inflammatory and oxidative markers in major depressive disorder disorder

Protocol summary

Summary

1- Objectives :Epidemiologic studies have shown that serum vitamin D is lower in patients with depression. The aim of this study is to determine effects of vitamin D supplementation on depression severity and inflammatory and oxidative factors in patients with major depressive disorder. 2-Design: Double blind randomized controlled trial. 3- Setting and conduct: Forty 18-65 year old patients with a diagnosis of major depressive disorder will be randomly allocated in two groups to receive 20 mg fluoxetine either alone or plus 1500 IU vitamin D for 8 weeks. Depression severity will be measured at baseline and after weeks 2, 4, 6, 8. Ten mL of venous blood sample will be obtained at baseline and after intervention and serum CRP and IL-6 and plasma total antioxidant will be measured. 4- Participants: Forty 18-65 year old patients with a diagnosis of major depressive disorder who were free of medication. 5- Intervention: 20 mg fluoxetine plus 1500 IU vitamin D or 20mg fluoxetine plus Placebo for 8 weeks. 6- Main outcome measures variables: Depression severity, serum C-reactive protein, Serum IL-6, plasma total antioxidant capacity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201072394N6**
Registration date: **2012-04-25, 1391/02/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-04-25, 1391/02/06

Registrant information

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Iran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-10-07, 1390/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplementation on depression severity, inflammatory and oxidative markers in major depressive disorder disorder

Public title

Effect of vitamin D in major depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Willing to participate; Clinical diagnosis of major depressive disorder; A score ≥15 in the 17-item Hamilton Depression Rating Scale; Age 18 – 65 years; Good health status based on medical history; No antidepressant or dietary supplement use during the

previous two months. Exclusion criteria: Substance abuse; Pregnancy and lactation.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Ethics committee of Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran, Iran.

City
Tehran

Postal code

Approval date
2010-10-10, 1389/07/18

Ethics committee reference number
2402

Health conditions studied

1

Description of health condition studied
Major depressive disorder

ICD-10 code
F32.2

ICD-10 code description
Major depression

Primary outcomes

1

Description
Depression severity

Timepoint
At baseline, weeks 2, 4, 6, 8

Method of measurement
Hamilton Depression Rating Scale

Secondary outcomes

1

Description
C-reactive protein

Timepoint
At baseline, after weeks 2, 4, 6, 8.

Method of measurement
ELISA

2

Description
Total antioxidant capacity

Timepoint
8 weeks

Method of measurement
FRAP

3

Description
IL-6

Timepoint
At baseline, after weeks 2, 4, 6, 8.

Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: 20 mg fluoxetine plus 1500 IU vitamin D daily after lunchfor 8 weeks

Category
Other

2

Description
Placebo group: 20 patients will receive 20 mg fluoxetin and placebo for 8 weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Psychiatry Hospital

Full name of responsible person

Dr.Mahdi Tehrani-Doost

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran, Iran

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for research, Tehran 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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Full name of responsible person

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Position

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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*