

# 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

#### 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

##### Name

Shima Jazayeri

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8670 4805

##### Email address

sjazayeri@razi.tums.ac.ir

##### 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

##### 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  $\geq 15$  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 lunch for 8 weeks

#### Category

Other

### 2

#### Description

Placebo group: 20 patients will receive 20 mg fluoxetine 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  
**City**  
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**  
Tehran University of Medical Science  
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Nayereh Khoraminy  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*

