# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Evaluating the effect of vitamine D in improvement rate of 18-65 years old patients with treatment resistant depression in ziaeian hospital in 2014

## Protocol summary


**Summary**

World Health Organization considers depression as one of the four major health problems worldwide and projections based on 2030 as the second leading cause of years of life adjusted for disability (DALYs). However, due to the widespread presence of vitamin D receptors in areas of the brain such as the hippocampus which is associated with depression, it can be taken that vitamin D is effective on depression. Based on the material and the clinical trials conducted we decided to investigate the effect of vitamin D supplementation on symptoms of treatment resistant depression in a clinical trial study on 64 patients eligible for inclusion to study which referred to Ziaeian hospital who randomly divided into two groups and placebo (n = 32 per group). The main objective of this study is to evaluate the effect of vitamin D in response to treatment of the first step of treatment resistant depression. Secondary objective was to determine the association of age with response to treatment with vitamin D - the relationship between sex and response to treatment with vitamin D - The effect of vitamin D on calcium and phosphorus and PTH levels in serum. This study is a randomized, double blind, placebo-controlled, single-center, and phase 2-3 clinical trials. Inclusion criteria: 18-65 year old patients with treatment resistant depression and known case of major depression disorder and under treatment with full dose Sertraline at least 4-6 weeks and does not respond to treatment. Also their 25-hydroxyvitamin D serum level must be lower than 50 nmol/L or les than 20 ng/ml. Exclusion criteria: patients with medical or psychiatric illnesses associated. Pregnant women, Lack of interest in participating in the study, and all contraindications of vitamin D, Bupropion tablets, calcium carbonate tablets. Intervention or interventions : Pre-intervention levels of serum 25-hydroxyvitamin D, calcium, PTH, phosphorus and alkaline phosphatase measured and based on the Hamilton depression rating scale score is determined. In both groups, the full dose of sertraline tablets continues. In addition to sertraline tablets, the group of vitamin D will take bupropion 450 mg tablet daily and orally for 3 months plus vitamin D, 50,000 IU pearl 12 ones, one per week up to 8 weeks and 1 per month up to 4 months and two calcium carbonate 500 mg tablets daily for 3 months. And the placebo group will take bupropion 450 mg tablet daily and orally for 3 months plus vitamin D placebo pearl 12 ones, one per week up to 8 weeks and 1 per month up to 4 months and two calcium carbonate 500 mg tablets daily for 3 months. After a period of 3 months, serum levels of 25-hydroxyvitamin D, calcium, PTH, phosphorus, alkaline phosphatase and also rating of depression based on the Hamilton questionnaire will be measured again. And the 2 groups will compare in terms of mentioned items. To continue treating people who were taking vitamin D supplements would be reminded to take 1 vitamin D pearl per month up to 3 months due to complete 12 pieces course of medication, and then to follow up with vitamin D deficiency or improvement should refer to the internal clinic. The primary outcome is the change in the Hamilton Rating Scale.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2014080315276N2**
Registration date: **2014-09-05, 1393/06/14**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2014-09-05, 1393/06/14

**Registrant information**

**Name**

Mohammad Effatpanah

**Name of organization / entity**
Tehran University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**
Tehran University of Medical Sciences

**Expected recruitment start date**
2014-09-06, 1393/06/15

**Expected recruitment end date**
2015-03-06, 1393/12/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluating the effect of vitamine D in improvement rate of 18-65 years old patients with treatment resistant depression in ziaeian hospital in 2014

**Public title**
Effect of vitamin D in improvement of depression

**Purpose**
Treatment

**Inclusion/Exclusion criteria**
Inclusion criteria: 18-65 year old patients with treatment resistant depression based on survey by psychologist and DSM IV criteria. The patients who entered the study must be known case of major depression disorder and under treatment with full dose Sertraline at least 4-6 weeks and not responding to treatment. Also their 25-hydroxyvitamin D serum level must be lower than 50 nmol/L or less than 20 ng/ml. Women of reproductive age with negative BHCG that use reliable method of contraception during the study. Exclusion criteria: patients with Sarcoidosis, Tuberculosis, Malignancy, Hypercalcemia, Renal disease (Nephrolithiasis, etc.); known case of malabsorption problems like celiac and etc. and other medical or psychiatric illnesses associated. Pregnant or lactating women are also excluded.

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

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **64**

**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**
6th floor, central building of university, Qods st, Keshavarz blv

**City**
Tehran

**Postal code**

**Approval date**
2014-07-15, 1393/04/24

**Ethics committee reference number**
93/130/917/د

## Health conditions studied

### 1

**Description of health condition studied**
Treatment – Resistant Depression

**ICD-10 code**
F32.1, F32

**ICD-10 code description**
Severe depressive episode without psychotic symptoms and Moderate depressive episode

### 2

**Description of health condition studied**
Vitamin D deficiency

**ICD-10 code**
E55

**ICD-10 code description**
Vitamin D deficiency

## Primary outcomes

### 1

**Description**
The degree of depression based on Hamilton Depression

Rating scale

**Timepoint**

Once before and once after three months of initial intervention

**Method of measurement**

Hamilton Depression Rating scale

## Secondary outcomes

### 1

**Description**

Phosphorus serum level mmol/L or mg/dl

**Timepoint**

Once before and once after three months of initial intervention

**Method of measurement**

Blood sample taking

### 2

**Description**

25-hydroxyvitamin D serum level nmol/L or ng/ml

**Timepoint**

Once before and once after three months of initial intervention

**Method of measurement**

Blood sample taking

### 3

**Description**

Calcium serum level mg/dl or mM

**Timepoint**

Once before and once after three months of initial intervention

**Method of measurement**

Blood sample taking

### 4

**Description**

Parathyroid hormoneserum level mmol/L or mg/dl

**Timepoint**

Once before and once after three months of initial intervention

**Method of measurement**

Blood sample taking

### 5

**Description**

Age

**Timepoint**

Once before initial intervention

**Method of measurement**

Observation

### 6

**Description**

Sex

**Timepoint**

Once before initial intervention

**Method of measurement**

Observation

## Intervention groups

### 1

**Description**

Bupropion 450 mg tablet, daily, oral, up to 3 month + Calcium carbonate 500 mg tablet,oral, BD, up to 3 month + vitamin D3 pearl oral, one perl per week up to 8 weeks and then one perl per month up to 4 month for intervention group.

**Category**

Treatment - Drugs

### 2

**Description**

Bupropion 450 mg tablet, daily, oral, up to 3 month + Calcium carbonate 500 mg tablet,oral, BD, up to 3 month + Placebo vitamin D3 pearl oral, one perl per week up to 8 weeks and then one perl per month up to 4 month for control group

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Ziaeian Hospital

**Full name of responsible person**

Assistant professor, Sub-specialist in child and adolescent psychiatry

**Street address**

Ziaeian Hospital. Opposite Municipality. Abouzar St.

**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. Masoud Yunesian

**Street address**

6th floor, Central building of university, Qods st, Keshavarz blv

**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 Sciences

**Full name of responsible person**

Mohammad Effatpanah

**Position**

Assistant professor, Sub-specialist in child and adolescent psychiatry

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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**Web page address**

## 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*