

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluating the effect of vitamin D in improvement rate of 18-65 years old patients with treatment resistant depression in Ziaei 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 Ziaei 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 less 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

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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 ziaiean 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

93/130/917/5

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
Ziaeeian Hospital
Full name of responsible person
Assistant professor, Sub-specialist in child and adolescent psychiatry
Street address
Ziaeeian Hospital. Opposite Municipality. Abouzar St.
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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
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6th floor, Central building of university, Qods st, Keshavarz blv
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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**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Effatpanah

Position

Assistant professor, Sub-specialist in child and adolescent psychiatry

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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