Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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

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Name of organization / entity
Tehran University of Medical Sciences

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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

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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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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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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