Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of vitamin D addition on treatment response in patients with schizophrenia in zare hospital

Protocol summary

Summary

Objectives: The purpose of the present study is to assess possible correlations between serum concentrations of vitamin D and disease activity in patients with schizophrenia treated with atypical antipsychotic except clozapine. Study Design and Population: This randomized clinical trial will be conducted at the Zare Mental Health Center, Sari, Iran. Eighty schizophrenic patients based on DSM-IV TR criteria will be included in the study if they are aged between 18 to 65 years, treated with atypical antipsychotic drugs except clozapine and Vitamin D deficiency (serum vitamin D concentrations less than 30 ng/ml) .Patients with Acute renal failure, hepatic failure, parathyroid disease and consumption of vitamin D, parathyroid hormone, calcium, and phosphorous supplements will be excluded from study. Intervention: If the patient meets our inclusion criteria, he is entered in the study. Randomization was applied for each treatment group(1:1).In Group A, 600000 IU vitamin D supplementation is added intramuscular to standard atypical antipsychotic drug regimens monthly for three months. In Group B, as control group, is received only standard atypical antipsychotic drug regimens. Patients in second group will be supplemented with vitamin D after the 3 months period. Measurements and outcomes: At the baseline visit and after three months, blood samples are drawn for analysis of serum vitamin D, calcium, phosphorous, creatinine, BUN and routine liver function tests. Schizophrenic symptoms are evaluated with Positive and Negative Syndrome Scale (PANSS) at baseline and monthly for three months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210163014N6**
Registration date: **2013-05-25, 1392/03/04**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-05-25, 1392/03/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Mazandaran University of Medical Sciences

Expected recruitment start date

2013-02-28, 1391/12/10

Expected recruitment end date

2015-02-28, 1393/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D addition on treatment response in patients with schizophrenia in zare hospital

Public title

The effect of vitamin D addition on treatment response in patients with schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Schizophrenic patients based on DSM-IV TR criteria ;aged between 18 to 65 years; treated with atypical antipsychotic drugs except clozapine ; Vitamin D deficiency (serum vitamin D concentrations less than 30 ng/ml) . Exclusion criteria: Patients with Acute renal failure; hepatic failure; parathyroid disease and consumption of vitamin D; parathyroid hormone; calcium and phosphorous supplements

Age

From **19 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethic committee of Mazandaran University of Medical Sciences and health services (MAZUMS)

Street address

18 KM Kazarabad Road, The Campus of Mazandaran University of Medical Sciences and health services (MAZUMS)

City

Sari

Postal code

Approval date

2013-02-02, 1391/11/14

Ethics committee reference number

911114

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20.6

ICD-10 code description

A disorder in which there is an insidious but progressive development of oddities of conduct, inability to meet the demands of society, and decline in total performance. The characteristic negative features of residual schizophrenia (e.g. blunting of affe

Primary outcomes

1

Description

Change in Positive and Negative Syndrome Scale total score (PANSS)

Timepoint

Baseline and first,second,third month

Method of measurement

PANSS Questionnaire

Secondary outcomes

1

Description

Serum vitamin D concentration

Timepoint

Baseline and third month

Method of measurement

ELISA

Intervention groups

1

Description

In Group A, 600000 IU vitamin D supplementation is added intramuscular to standard atypical antipsychotic drug regimens monthly for three months.

Category

Treatment - Drugs

2

Description

In Group B, as control group, is received only standard atypical antipsychotic drug regimens. Patients in second group will be supplemented with vitamin D after the 3 months study period.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zare Mental Health Center

Full name of responsible person
Dr. Narjes Hendouei
Street address
5 KM Neka-Sari Road
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Mazandaran University of Medical Sciences
Full name of responsible person
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18 KM Khazarabad Road, Faculty of pharmacy, Mazandaran University of Medical Science
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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,Mazandaran 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

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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