

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Name

Shahram Ala

Name of organization / entity

Mazandaran University of Medical Sciences

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Iran (Islamic Republic of)

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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 affect)

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

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5 KM Neka-Sari Road

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice chancellor for research,Mazandaran University of
Medical Sciences**Full name of responsible person**

Dr. Shahram Ala

Street address18 KM Khazarabad Road, Faculty of pharmacy,
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice 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****Contact****Name of organization / entity**

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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