

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 15 1354 3083

###### Email address

sala@mazums.ac.ir

##### 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

shima.mamashli67@gmail.com

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Narjes Hendouei

**Position**

Clinical pharmacy specialist, Assistant professor

**Other areas of specialty/work****Street address**

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hendoieen@yahoo.com

**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 address**

18 KM Khazarabad Road, Faculty of pharmacy,  
Mazandaran University of Medical Science

**City**

Sari

**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****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Shima Mamashli

**Position**

Pharmacy student

**Other areas of specialty/work****Street address**

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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*