

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The comparison of effectiveness of vitamin D3 supplement with placebo on reducing the rate of weight gain due to consuming of olanzapine in the women with psychiatric disorders.

#### Protocol summary

##### Summary

The comparison of effectiveness the vitamin D3 supplement with placebo on reducing the rate of weight gain due to consuming olanzapine in the women with psychiatric disorders. Inclusion criteria:women with psychiatric disorder;20-55 years old ;not pregnant;have not any medical illness;during consuming olanzapin have weight gain;her serum level of vitamin is normal range and having normal weight before receiving olanzapin. Exclusion criteria:women with medical illness;poly cystic ovarian and women that received other drug that induced obesity. this study is on 50 women that have psychiatric disorder. this study is an interventional ,double blind,placebo control clinical trial which one group of them receive vitamin D3,and other group receive placebo every 2 week for 12 week. height, weight, wrist and BMI measured before and after investigation and then will be analyzed. The primary outcome are Weight,BMI,Wrist,Hip,Wrist hip ratio.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014122520430N1**

Registration date: **2015-02-02, 1393/11/13**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-02-02, 1393/11/13

##### Registrant information

##### Name

Somayeh kaviyani Dastgerdi

##### Name of organization / entity

Jundishapur University of Ahvaz

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3374 3001

##### Email address

kaviyani.s@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research of ahvaz University of Medical Sciences

##### Expected recruitment start date

2013-03-20, 1391/12/30

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of effectiveness of vitamin D3 supplement with placebo on reducing the rate of weight gain due to consuming of olanzapine in the women with psychiatric disorders.

##### Public title

The effect of vitamin D3 on the obesity

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria:women with psychiatric disorder;20-55 years old;not pregnant;have not any medical illness;during consuming olanzapin have weight gain;her serum level of vitamin is normal range. Exclusion

criteria:women with medical illness;poly cystic ovarian and women that receive other drug that induced obesity.

### Age

From **20 years** old to **55 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **50**

### 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 Ahvaz University Of Medical Science.

##### Street address

Golestan street, West Coast Blvd, Ahvaz

##### City

Ahvaz

##### Postal code

#### Approval date

2013-07-27, 1392/05/05

#### Ethics committee reference number

ajums.rec.1393.347

## Health conditions studied

### 1

#### Description of health condition studied

drug induced obesity

#### ICD-10 code

E66.1

#### ICD-10 code description

Use additional external cause code (Chapter XX), if desired, to identify drug.

## Primary outcomes

### 1

#### Description

Weight,BMI,Wrist,Hip,Wrist hip ratio.

#### Timepoint

Befor and after intervention

#### Method of measurement

Befor and after intervention with Scales and meters

## Secondary outcomes

### 1

#### Description

Nusea,Headache

#### Timepoint

Befor intervention

#### Method of measurement

During intervention repeatedly

## Intervention groups

### 1

#### Description

Drug group:pearl 50000 unit, vitamin D3,that every 2 week prescribe to 12 week

#### Category

Treatment - Drugs

### 2

#### Description

Control : placebo of vitamin D3,that every 2 week prescribe to 12 week.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Golestan Hospital Of Ahvaz

##### Full name of responsible person

Kaviyani Somayeh

##### Street address

Golestan Hospital ,Golestan street ,West Coast Blvd ,Ahvaz.

##### City

Ahvaz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University Of Medical Science

##### Full name of responsible person

Dr.Nadereh Saki

**Street address**

Research Administration, Ahvaz University Of Science,  
Ahvaz.

**City**

Ahvaz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz University Of Medical Science

**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**

Ahvaz University Of Medical Science

**Full name of responsible person**

Kaviyani Somayeh

**Position**

Psychiatric Resident

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

Golestan Hospital, Golestan Street, West Coast Blvd,  
Ahvaz.

**City**

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**Postal code****Phone**

+98 61337430019

**Fax****Email**

kaviyani\_somayeh@yahoo.com;  
kaviyani.s@ajums.ac.ir; jazayeri902@yahoo.com

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

Ahvaz University Of Medical Science

**Full name of responsible person**

Kaviyani Somayeh

**Position**

Psychiatric Resident

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University Of Medical Science

**Full name of responsible person**

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**Fax****Email**

kaviyani\_somayeh@yahoo.com;  
kaviyani.s@ajums.ac.ir; jazayeri90@yahoo.com.

**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*