

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

Ahvaz

Postal code**Phone**

+98 61337430019

Fax**Email**

kaviyani_somayeh@yahoo.com;
kaviyani.s@ajums.ac.ir; jazayeri902yahoo.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

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

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

City

Ahvaz

Postal code**Phone**

+98 61337430019

Fax**Email**

kaviyani_somayeh@yahoo.com;
kaviyani.s@ajums.ac.ir; jazayeri90@yahoo.com.

Web page address**Person responsible for updating data****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

Ahvaz

Postal code**Phone**

+98 61337430019

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