

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The efficacy of Vitamin D supplementation in the treatment of schizophrenia

Protocol summary

Summary

In this randomized clinical trial 70 patients with schizophrenia according to DSM-V criteria was divided randomly in two groups. In first group as a intervention group 35 patients received 20-25 mg olanzapine for 3 Months and 300000 IU Vitamin D as IM Injection Form for 1 Time. and other group with the same follow up received 20-25 mg olanzapine and placebo .in each group FBS,cratinin ,ca,pr ,parathormon hormone and Positive and Negative Syndrome Scale (PANSS)Criteria at the first and the 1,2,3 Months was measured and com paired.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507087373N5**

Registration date: **2017-05-14, 1396/02/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-14, 1396/02/24

Registrant information

Name

Hamidreza Jamilian

Name of organization / entity

Arak University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1222 5758

Email address

jamilian.hr@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2015-08-01, 1394/05/10

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Vitamin D supplementation in the treatment of schizophrenia

Public title

The efficacy of Vitamin D supplementation in the treatment of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of schizophrenia according to DSM-5 criteria ,age range 18-68 ,a score of at least 60 in PANSS Exclusion criteria:Mental Retardation; Organic brain disease; Parathyroid disorders; Use of Vitamin D Supplementation in recent 3 months; Pregnancy and Lactation; Vitamin D metabolism disorders; serum level of Vitamin D below 10 nmol/ml; serum level of Vitamin D over 100 nmol/ml; No interest to continue treatment; substance abuse; GFR below 60 ml/min; No response to previous treatment with Olanzapin; BMI over 30

Age

From **18 years** old to **68 years** old

Gender

Both

Phase

1
Groups that have been masked
No information
Sample size
Target sample size: 70
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 Arak University of Medical Sciences
Street address
Basij Square
City
ARAK
Postal code
Approval date
2015-06-29, 1394/04/08
Ethics committee reference number
IR.ARAKMU.REC.1394.93

Health conditions studied

1
Description of health condition studied
Schizophrenia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

Primary outcomes

1
Description
Positive and Negative Syndrome Scale(PANSS)
Timepoint
Before intervention and every one month for 3 months
Method of measurement
Clinical Examination

Secondary outcomes

1
Description
extrapyramidal side effects
Timepoint
before intervention and every one month for 3 months
Method of measurement
clinical exam

Intervention groups

1
Description
Intervention group: receive olanzapin 10-25 mg/d for 3 months with vitamin D 300000 IU IM at the beginning of intervention.
Category
Treatment - Drugs

2
Description
control group: receive olanzapine 10-25 mg/d for 3 months with placebo at the beginning of intervention.
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
amir kabir hospital and emam reza clinic
Full name of responsible person
hamidreza jamilian
Street address
amir kabir hospital and emam reza clinic
City
arak

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Vice chancer for research , Arak University of Medical Sciences
Full name of responsible person
Dr.yaghoobi
Street address
Basij Square
City
ARAK
Grant name
-
Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancer for research , Arak 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
Arak University of Medical Sciences

Full name of responsible person
Hamidreza Jamilian

Position
Board of Psychiatry, Associate Professor

Other areas of specialty/work

Street address
Amir Kabir Hospital

City
ARAK

Postal code

Phone
+98 86 3313 5075

Fax

Email
jamilian.hr@arakmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
HamidReza Jamilian

Position

Board of Psychiatry

Other areas of specialty/work

Street address
Amir Kabir Hospital

City
ARAK

Postal code

Phone
+98 86 3313 5075

Fax

Email
jamilian.hr@arakmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Hamidreza Jamilian

Position
Board of Psychiatry ,Associate Professor

Other areas of specialty/work

Street address
Amir kabir Hospital

City
ARAK

Postal code

Phone
00

Fax

Email

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