

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effectiveness of vitamin D supplementation on schizophrenia symptoms

Protocol summary

Study aim

Investigating the effectiveness of vitamin D supplementation on schizophrenia symptoms

Design

The dose of vitamin D supplement is 50,000 IU weekly. It is considered for 12 weeks, and after 12 weeks (three months from the start of taking the supplement), the supplement is taken once a month until the end of the 24th week (6 months from the start of taking the supplement). Before and after the end of the study, i.e. after 12 weeks (3 months) and again at the end of the 24th week (6 months), vitamin D levels and PANSS and MoCA questionnaires will be measured and implemented for all participants

Settings and conduct

The present study is conducted in a period of 24 weeks with the participation of 72 patients with schizophrenia and vitamin D deficiency who referred to the Yazd Psychiatric Hospital clinic

Participants/Inclusion and exclusion criteria

Inclusion in the study included the diagnosis of chronic outpatient schizophrenia (at least three years since the onset of the disease and at least one year under treatment with antipsychotic drugs) based on DSM5 by a psychiatrist, obtaining a score by the questionnaire (PANSS) above 70, vitamin D level below 30ng, and Exclusion criteria included receiving ECT in the past two months

Intervention groups

Using random codes obtained from the computer, people are divided into two groups of vitamin D supplement users or placebo. Each group will have 36 people and a total of 72 people will participate in the study

Main outcome variables

Symptom improvement, prevention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231109060002N1**
Registration date: **2023-11-23, 1402/09/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-23, 1402/09/02**

Update count: **0**

Registration date

2023-11-23, 1402/09/02

Registrant information

Name

Malihe Samsami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3263 2004

Email address

samsami.psy@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-11-21, 1403/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of vitamin D supplementation on schizophrenia symptoms

Public title

The effectiveness of vitamin D supplementation on schizophrenia symptoms

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of chronic outpatient schizophrenia (at least three years have passed since the onset of the disease and at least one year under treatment with antipsychotic drugs) based on DSM5 by a psychiatrist Vitamin D level below 30ng under treatment for at least 8 weeks with a fixed dose of the drug score question (PANSS) above 70

Exclusion criteria:

Received ECT in the past two months Mental retardation Organic brain disease and history of head trauma History of drug and alcohol use Non-cooperation in filling out the questionnaire Non-cooperation in taking medicine or changing its dosage Non-cooperation in taking vitamin D supplements Kidney, heart, thyroid disorders and diseases, hemorrhagic diseases and malignancies Pregnancy and breastfeeding

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants are randomly divided into each intervention and control group by simple random method using the RAND function of Excel software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The method of blinding the participants, researchers and the statistical analyzer of the plan to the intervention pills is that for this purpose, the manufacturer packs the capsules in similar packages and identifies them with the names A and B. Until after the researchers study, the participants and the statistical analyzer do not know about their nature, and a trusted expert will know about the main nature of the supplement and placebo until the end of the project

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Vice President of Research and Technology, Shahid Sadoughi University of Medical Sciences., First of Imam Reza Educational Research Building., Student Bld., Imam Hossein Sq., YAZD

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Yazd

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8916188637

Approval date

2023-11-08, 1402/08/17

Ethics committee reference number

IR.SSU.REC.1402.064

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Montreal Mocha cognitive test MoCA

Timepoint

The beginning of the study, the end of week 12, the end of week 24

Method of measurement

Moka cognitive assessment questionnaire is measured and implemented for all participants by a clinical psychologist.

2

Description

PANSS positive and negative symptom evaluation test

Timepoint

The beginning of the study, the end of week 12, the end of week 24

Method of measurement

The questionnaire for evaluating positive and negative symptoms of schizophrenia is measured and

implemented by a clinical psychologist for all participants.

3

Description

Vitamin D serum level

Timepoint

The beginning of the study, the end of week 12, the end of week 24

Method of measurement

In order to perform laboratory tests before and after the intervention, 10 cc of venous blood will be collected, its serum will be separated and removed. All tests are performed in a single laboratory in a public hospital. Prescribing the test and interpretation of the results will be done by the psychiatrist of Yazd Psychiatric Hospital

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: According to previous studies, the dose of vitamin D supplement is 50,000 IU weekly for 12 weeks, and after 12 weeks (three months from the start of taking the supplement), the supplement is taken once a month. It is consumed until the end of the 24th week (6 months from the start of taking the supplement). At the beginning of the study and at the end of the 12th week and at the end of the 24th week, the level of vitamin D and the score of the psychological tests are evaluated.

Category

Other

2

Description

Control group: Placebo (sunflower oil) with the same packaging as a 50,000 IU dose supplement is considered weekly. It is considered weekly for a period of 12 weeks, and after 12 weeks (three months from the start of taking the placebo), the placebo is taken once a month until the end of the 24th week (6 months from the start of taking the placebo). At the beginning of the study, at the end of the 12th week and at the end of the 24th week, the level of vitamin D and the score of the psychological tests are evaluated.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized psychiatric hospital of Yazd

Full name of responsible person

Malihe Samsami

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Yazd Specialized Psychiatric Hospital., Shahid Beheshti Blv., Taft., YAZD

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abargouei

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

80

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Malihe Samsami

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available