Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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)

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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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Postal code
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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Sponsors / Funding sources

1

Sponsor
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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