Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of the vitamin D3 on the metabolic parametrs, serum levels of the glycogen synthase kinase-3, β catenin, BDNF, S100B and ZAG in schizophrenic patients who have vitamin D3 deficiency

Protocol summary

Study aim

Determining the effect of vitamin D3 supplementation on metabolic parameters, serum glycogen synthase kinase 3, beta-catenin, BDNF, S100B and ZAG levels in patients with schizophrenia deficient in vitamin D3

Design

This study was conducted in a controlled clinical trial with parallel, blind, randomized groups. Randomization process will be done with using a random number table. Participants will enter into one of the following groups: 1) The group receiving the vitamin D3 supplement 2) The placebo group The sample size is 46

Settings and conduct

This study was carried out in Razi Hospital in Tabriz on schizophrenia patients randomly assigned to the both intervention and control groups as well as the patients , researchers and nurses will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria People with schizophrenia admitted to Razi Hospital, The age range of 18-65 years old in men and the age range of 18-50 years in women, Diagnosis of schizophrenia based on the DSM-V , PANSS score above 70, no receive any oral or inject able dietary supplements over the past year , The serum level of vitamin D3 below 20 ng / ml, The desire to participate in the study Non-entry criteria Pregnancy or breastfeeding, co morbidity of the other major psychological or neurological diseases , Smoking and alcohol consumption , History of the compliance with certain diets

Intervention groups

People of the group (1) will receive vitamin D3 with a dose of 2000 IU. The control group will receive the placebo, which the appearance is quite similar to the original drug

Main outcome variables

Improvement of metabolic indexes and psychological functions of the disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190313043039N1**
Registration date: **2019-04-19, 1398/01/30**
Registration timing: **prospective**

Last update: **2019-04-19, 1398/01/30**
Update count: **0**

Registration date

2019-04-19, 1398/01/30

Registrant information

Name

parinaz kalejahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3669 9091

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of the vitamin D3 on the metabolic parametrs, serum levels of the glycogen synthase kinase-3, β catenin, BDNF, S100B and ZAG in schizophrenic patients who have vitamin D3 deficiency

Public title
Effect of vitamin D supplements in schizophrenia

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
People with schizophrenia admitted to Razi Hospital The age range of 18-65 years old in men and the age range of 18-50 years in women Diagnosis of schizophrenia based on the DSM-V (Diagnostic and Statistical Manual of Mental Disorders, 5th Edition) and Psychiatrist's Confirmation PANSS score above 70 Did not receive any dietary supplements (oral or injectable) in the past year(such as vitamin D3 and calcium) Serum levels of the vitamin D3 below 20 ng / ml The desire to participate in the study

Exclusion criteria:
Pregnancy or breastfeeding comorbididty with other major psychological or neurological diseases such as bipolar disorder and multiple sclerosis Smoking and alcohol consumption History of compliance with certain diets Use of serum vitamin D suppressants (such as anticonvulsants and glucocorticoids)

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
A total of 46 patients admitted to Razi Hospital in Tabriz were selected by simple sampling.In order to blinding, extraction of random numbers and their readings and assignment to the two groups (the odd numbers of the control group, paird numbers of the intervention group) will be carried out by the assistant researcher; The number of 46 envelopes with numbers 1 to 46 was prepared and inside them the numbers extracted from the random numbers table

Blinding (investigator's opinion)
Double blinded

Blinding description
Vitamin D and their placebo will be prepared by the pharmaceutical company in a completely similar shape, color and smell. The sequencing of allocation and preparation of pills will be done by non-contributing people.The type of the medications (vitamin D or placebo) will not be known to the researcher, nurses and patients.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Attar Nishabouri St., Tabriz, I. R. Iran.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Approval date
2019-03-12, 1397/12/21

Ethics committee reference number
IR.TBZMED.REC.1397.1025

Health conditions studied

1

Description of health condition studied
SCHIZOPHRENIA

ICD-10 code
F20

ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Components of metabolic syndrome including waist circumference, fasting blood glucose, HDL, triglyceride and blood pressure

Timepoint
Before the intervention and 8 weeks later

Method of measurement
Accordingly, the bandwidth (waist circumference), kit and autoanalyser (sugar, HDL and triglyceride) and mercury pressure gauge (blood pressure)

Secondary outcomes

1

Description
Serum levels of glycogen synthase kinase 3, beta-catenin, BDNF, S100B and ZAG
Timepoint
Before the intervention and 8 weeks later
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: Patients with schizophrenia who receive a dose of 2000 IU Vitamin D(Prepared by Dana Pharmaceuticals Inc.) per day(after lunch).
Category
Treatment - Drugs

2

Description
Control group:Schizophrenic patients who are randomly assigned to the control group and will receive a placebo (provided by the Dana Pharmaceuticals Company) for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital in Tabriz
Full name of responsible person
Parinaz Kalejahi
Street address
Tabriz university of medical sciences
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5138765878
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Email
parinaz.kalejahi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Abolqasem Jouyban
Street address
Azad Street, Golgasteh Street, Central Building No. 2 of the University
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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
Tabriz University of Medical Sciences
Proportion provided by this source
100
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
Tabriz University of Medical Sciences
Full name of responsible person
Parinaz Kalejahi
Position
Ph.D. student
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

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

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Requested data will be provided to researchers for statistical analysis of the submitted proposal.

When the data will become available and for how long
Start the access period immediately after printing the results

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
-

From where data/document is obtainable
Refer to the email address

What processes are involved for a request to access data/document
Requests will be sent by email and the data will be available after checking the email

Comments