

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Clinical trial of the effect of combined probiotic and vitamin D supplementation compared with the placebo on Clinical symptom and metabolic profiles in schizophrenia patients

Protocol summary

Study aim

The aim of this study is to determine the effects of combined probiotic and vitamin D supplementation on Clinical symptom and metabolic profiles in schizophrenia patients.

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct

Population and sample size: 60 patients with schizophrenia of eligible and referred to Karganejad hospital to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosed with schizophrenia using DSM-IV-TR criteria, treated with chlorpromazine (300-1000mg/day, except clozapine) and agents anti-cholinergic (Trihexyphenidyl, 4-8 mg/day) during the last 6 months, aged 25-65 years old. Exclusion criteria: Mental retardation, substance or alcohol addiction (except caffeine or nicotine) with in the last 6 months of screening, A score of ≥ 14 on a 17-item Hamilton Depression Rating Scale or a score of ≥ 4 on PANSS (depression item), under treatment with lithium, carbamazepine and sodium valproic acid, existing chronic and acute medical illness.

Intervention groups

Intervention: Patients will be assigned into two groups to receive combined probiotic and vitamin D (n=30) or placebo (n=30). Probiotic, vitamin D and placebos capsules are similar in shape and size.

Main outcome variables

Clinical symptom (primary outcomes), and metabolic profiles (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072333551N2**

Registration date: **2017-07-31, 1396/05/09**

Registration timing: **retrospective**

Last update: **2019-09-15, 1398/06/24**

Update count: **1**

Registration date

2017-07-31, 1396/05/09

Registrant information

Name

Amir Ghaderi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 918 771 7435

Email address

ghaderi-am@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-05-04, 1396/02/14

Expected recruitment end date

2017-06-04, 1396/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of combined probiotic and vitamin D supplementation compared with the placebo on Clinical symptom and metabolic profiles in schizophrenia patients

Public title
Effect of supplementation in treatment of schizophrenia patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosed with schizophrenia using DSM-IV-TR criteria PANSS score of 55 or greater Treated with chlorpromazine (300–1000mg/day, except clozapine) and agents anti-cholinergic (Trihexyphenidyl, 4–8 mg/day) during the last 6 months Aged 25–65 years old Disease duration of at least two years
Exclusion criteria:
Mental retardation Substance or alcohol addiction (except caffeine or nicotine) with in the last 6 months of screening A score of ≥ 14 on a 17-item Hamilton Depression Rating Scale or a score of ≥ 4 on PANSS (depression item) Under treatment with lithium, carbamazepine and sodium valproic acid Existing chronic and acute medical illness Lactation or pregnancy The use of anti-depressants including MAO, TCA, SSRI in the last 6 months

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed with simple method and random numbers generated by computer software (Stat Trek software) which choose the random numbers. Then, we consider the specific numbers for both groups for example: the even numbers are for intervention group and the odd numbers are for the placebo group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo has been used to achieve masking of participants and investigators. The researchers and patients will be concealed until the final analyses by a trained staff.

Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfahan
Postal code
8814187159
Approval date
2017-05-03, 1396/02/13
Ethics committee reference number
IR.Kaums.REC.1396.10

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
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Clinical Examination

Secondary outcomes

1

Description
Fasting plasma glucose
Timepoint
At the beginning of the study and after 12 weeks of

intervention
Method of measurement
Enzymatic kit

2

Description
Insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

3

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
Hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

7

Description
Total antioxidant
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

9

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: Combined probiotic, including 2×10⁹ Lactobacillus acidophilus, 2×10⁹ Bifidobacterium bifidum, 2×10⁹ Lactobacillus reuteri, 2×10⁹ Lactobacillus fermentum daily, and vitamin D supplements (Zahravi, Tabriz, Iran), 50,000 IU vitamin D every 2 weeks, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Probiotic and vitamin D placebos capsule (Barij essence, Kashan, Iran), probiotic placebo daily and vitamin D placebo every 2 weeks, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kargarnejad Hospital
Full name of responsible person
Fatemeh Sadat Ghoreishi
Street address
Ghotbe Ravandi Boulevard, Kargarnejad hospital, Psychiatry clinic, Kashan
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Web page address
<http://kargarnejad.kaums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person
Hamid Reza Banafshe

Street address
Ghotbe Ravandi Boulevard, Kashan

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8814187159

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Email
banafshe57@hotmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Zatollah Asemi

Position
PhD of Nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Zatollah Asemi

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Person responsible for updating data

Contact

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Kashan University of Medical Sciences

Full name of responsible person
Zatollah Asemi

Position
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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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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