Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of probiotic capsule supplementation on severity depression among patients with major depressive disorder under treatment with citalopram

Protocol summary

Study aim

The aim of this study is to determine the effect of probiotic capsule supplementation on severity depression among patients with major depressive disorder under treatment with citalopram.

Design

Among patients with major depressive referred to the Kargarneghad Clinic affiliated to Kashan Medical Sciences University, Kashan, Iran, 40 patients will be selected. The study will be double blind in which participants and investigators/the assessors of the outcomes are unaware of the study groups and drug and placebo are similar. Fasting blood samples will be taken at baseline and end of the intervention. Intervention period: 8 weeks.

Settings and conduct

40 patients with major depressive disorder 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: Patients with major depressive, aged between 20 to 55 years. Exclusion criteria: Age <20 y or >55 y; a history of coronary infarction, angina pectoris, pregnancy or lactation, substance abuse; taking dietary supplements or probiotic supplements during the previous 2 months

Intervention groups

Patients will be assigned to receive either the probiotic capsule (intervention group: n=20) or placebo capsule (control group: n=20).

Main outcome variables

Beck Depression Inventory (primary outcome), and glycemic control, lipid profiles, biomarkers of inflammation and oxidative stress (secondary outcomes)

General information

Reason for update

Due to an error, the request for an update in our website has conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT2014060717993N1**
Registration date: **2014-11-04, 1393/08/13**
Registration timing: **retrospective**

Last update: **2020-10-12, 1399/07/21**
Update count: **1**

Registration date

2014-11-04, 1393/08/13

Registrant information

Name

Zahra Kashanipoor

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

TAK GENE ZIST Co , Tehran , Iran. Kashan University of Medical Sciences.

Expected recruitment start date

2014-07-01, 1393/04/10

Expected recruitment end date
2014-07-15, 1393/04/24
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of probiotic capsule supplementation on severity depression among patients with major depressive disorder under treatment with citalopram

Public title
The effect of probiotic capsule supplementation on severity depression
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with major depressive Aged between 20 to 55 years
Exclusion criteria:
Age <20 y or >55 years A history of coronary infarction Angina pectoris Pregnancy or lactation Substance abuse Taking dietary supplements or probiotic supplements during the previous 2 months
Age
From **20 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 40 by a random number generator (https://stattrek.com/statistics/random-number-generator.aspx) and patients will be randomly assigned into each intervention group by their numbers. The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Clinic, who is not involved in the trial and not aware of random sequences, will assign the participants to the numbered bottles of drugs. Supplements and placebos are in the same packaging at the Tak Gen Zist pharmaceutical company. Only the code is written on the packages. Patients and researcher will not know the type of intervention. After analyzing the data, pocket codes will be decoded. Participants and investigators/the assessors of the outcomes are unaware of the study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kashan University of Medical Sciences
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8715988141
Approval date
2014-06-09, 1393/03/19
Ethics committee reference number
93044

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F32
ICD-10 code description
Depressive episode

Primary outcomes

1

Description
Severity depression
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Questionnaire Beck

Secondary outcomes

1

Description
Insulin resistance
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Calculation using the Homeostasis Model Assessment (HOMA) formula

2

Description
Insulin
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
ELISA kit

3

Description
Fasting plasma glucose
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Total cholesterol
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
Triglycerides
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
High-density lipoprotein (HDL)
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

7

Description
Low-density lipoprotein (LDL)
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

8

Description
High-sensitivity C-reactive Protein (hs-CRP)
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
ELISA kit

9

Description
Glutathione
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

10

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Multi species probiotic capsules containing Lactobacillus acidophilus 2× 109 CFU, Lactobacillus casei 2× 109 CFU, Bifidbacterium bifidum 2 × 109 CFU.
Category
Placebo

2

Description
Control group: Placebo capsule, daily, for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kargarnejad Hospital

Full name of responsible person
Dr. Zahra Kashani-Poor
Street address
Ghotbe Ravandi Boulevard, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Department of Kashan University of Medical Sciences
Full name of responsible person
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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
Research Department of 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
Research Department of Kashan University of Medical Sciences
Full name of responsible person
Dr. Gholam Ali Hamidi
Position
Ph.D. (Physiology)
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
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Person responsible for updating data

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Dr. Zahra Kashani-Poor
Position

Resident in Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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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

Not applicable