

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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)

Phone

+98 31 5554 1112

Email address

zkashani@kaums.ac.ir

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

Isfahan

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, Bifidobacterium 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

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5546 3378

Email

zkashani@kaums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Department of Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5546 3378

Email

zkashani@kaums.ac.ir

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

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Phone

+98 31 5554 2999

Fax

+98 31 5557 5057

Email

hamiidi@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Dr. Zatollah Asemi

Position

PhD in Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Phone

+98 31 5546 3378

Fax**Email**

asemi_r@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Dr. Zahra Kashani-Poor

Position

Resident in Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715973446

Phone

+31 55549111

Fax

Email

zkashani313@gmail.com

Web page address

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