

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Effect of Probiotic supplementation on oxidative stress in patients with Major Depressive Disorder

Protocol summary

Summary

The aim of this study is to determine the effect of Probiotic capsule supplementation on oxidative stress in patients with Major Depressive Disorder under treatment with Fluoxetine. study design: randomized double-blinded controlled clinical trial. Inclusion Criteria: patients with Major Depressive based on DSM-IV-TR criteria that they have not used any nutritional supplements, antiinflammatory and antidepressant drugs at least 2 months prior to intervention; aged 18 to 65 years; at least score 15 on Hamilton Depression Rating Scale 17 (HDRS-17). Exclusion Criteria: pregnancy and lactation; drug abuse within 6 months prior to intervention; psychosis; any type of severe chronic physical illness; any extreme and severe mental disorders (suicidal ideation, psychotic symptoms, symptoms of manic phase, etc); compliance rate less than% 80; consuming Probiotic foods during intervention. population and sample size: 44 patients with Major Depressive Disorder of eligible and referred from Roozbeh hospital to Tehran University of Medical Sciences. intervention: patients will be assigned to receive either the probiotic capsule (intervention group: n=22) or placebo capsule (control group: n=22). blood samples will be taken at baseline and after 8-wk intervention. intervention: 8 weeks. Outcomes: Serum Catalase, Arylstrase activity of Paraxonase, Homocystein, Oxidized-LDL, MDA, hs-CRP and plasma Fibrinogen will be measured at the beginning and end of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611292394N34**

Registration date: **2017-01-02, 1395/10/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-02, 1395/10/13

Registrant information

Name

Shima Jazayeri

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4805

Email address

sjazayeri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Probiotic supplementation on oxidative stress in patients with Major Depressive Disorder

Public title

Effect of Probiotic supplementation on oxidative stress

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: patients with Major Depressive based on DSM-IV-TR criteria that they have not used any nutritional supplements, antiinflammatory and antidepressant drugs at least 2 months prior to intervention; aged 18 to 65 years; at least score 15 on Hamilton Depression Rating Scale 17 (HDRS-17).

Exclusion Criteria: pregnancy and lactation; drug abuse within 6 months prior to intervention; psychosis; any type of severe chronic physical illness; any extreme and severe mental disorders (suicidal ideation, psychotic symptoms, symptoms of manic phase, etc); compliance rate less than% 80; consuming probiotic foods during intervention.

Age

From **77 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmet Highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-11-19, 1395/08/29

Ethics committee reference number

IR.IUMS.REC.1395.9313680001

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Catalase

Timepoint

Beginning and end of intervention

Method of measurement

Colorimetry

2

Description

Homocystein

Timepoint

Beginning and end of intervention

Method of measurement

ELIZA

3

Description

Oxidized -LDL

Timepoint

Beginning and end of intervention

Method of measurement

ELIZA

4

Description

MDA

Timepoint

Beginning and end of intervention

Method of measurement

Colorimetry

5

Description

Arylstrase activity of Paraxonase

Timepoint

Beginning and end of intervention

Method of measurement

Colorimetry

6

Description

hs-CRP

Timepoint

Beginning and end of intervention

Method of measurement

ELIZA

7

Description

Fibrinogen

Timepoint

Beginning and end of intervention

Method of measurement

Coagulation

Secondary outcomes

1

Description

Energy intake

Timepoint

Beginning and end of intervention

Method of measurement

24-hour recall

2

Description

Physical activity

Timepoint

Beginning and end of intervention

Method of measurement

IPAQ questionnaire

3

Description

Side effect

Timepoint

End of fourth week and end of intervention

Method of measurement

Side effect questionnaire

4

Description

Weight

Timepoint

Beginning and end of intervention

Method of measurement

Scale

Intervention groups

1

Description

Control, Placebo

Category

Placebo

2

Description

Intervention, Multi species Probiotic capsules containing 3×10⁹ CFU Lactobacillus Helveticus and Bifidobacterium Longum

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital, Tehran University of Medical Science

Full name of responsible person

Shirin Tajadod

Street address

Roozbeh hospital, South Kargar Ave, Enghelab Sq, Tehran, Iran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Javad Moosavi

Street address

Vice chancellor for research, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran.

City

Tehran

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, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Nutrition, School of Public Health, Iran
University of Medical Sciences.

Full name of responsible person

Shirin Tajadod

Position

MSc Student of Nutrition

Other areas of specialty/work**Street address**

Department of Nutrition, School of Public Health, Iran
University of Medical Sciences, Shahid Hemmat
Highway, Tehran, Iran.

City

Tehran

Postal code**Phone**

+98 21 8670 4805

Fax**Email**

tajadod.shirin@yahoo.com

Web page address**Fax****Email**

sh_jaz@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Nutrition, School of public Health, Iran
University of Medical Science

Full name of responsible person

Shirin Tajadod

Position

MSc Student of Nutrition

Other areas of specialty/work**Street address**

Department of Nutrition, School of Public Health, Iran
University of Medical Sciences, Shahid Hemmat
Highway, Tehran, Iran.

City

Tehran

Postal code**Phone**

00

Fax**Email**

tajadod.shirin@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Nutrition, School of Public Health, Iran
University of Medical Sciences

Full name of responsible person

Dr. Shima Jazayeri

Position

MD, PhD.

Other areas of specialty/work**Street address**

Department of Nutrition, School of Public Health, Iran
University of Medical Sciences, Shahid Hemmat
Highway, Tehran, Iran.

City

Tehran

Postal code**Phone**

+98 21 8670 4805

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty