Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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 committe 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

Begining and end of intervention

Method of measurement

Colorimetry

2

Description

Homocystein

Timepoint

Begining and end of intervention

Method of measurement

ELIZA

3

Description

Oxidized -LDL

Timepoint

Begining and end of intervention

Method of measurement

ELIZA

4

Description

MDA

Timepoint

Begining and end of intervention

Method of measurement

Colorimetry

5

Description

Arylstrase activity of Paraxonase

Timepoint

Begining and end of intervention

Method of measurement

Colorimetry

6

Description
hs-CRP
Timepoint
Begining and end of intervention
Method of measurement
ELIZA

7

Description
Fibrinogen
Timepoint
Begining and end of intervention
Method of measurement
Coagulation

Secondary outcomes

1

Description
Energy intake
Timepoint
Begining and end of intervention
Method of measurement
24-hour recall

2

Description
Physical activity
Timepoint
Begining and end of intervention
Method of measurement
IPAQ questionnaire

3

Description
Side effect
Timepoint
End of forth week and end of intervention
Method of measurement
Side effect questionnaire

4

Description
Weight
Timepoint
Begining 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 Bifidbacterium 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
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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
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Other areas of specialty/work

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Person responsible for scientific inquiries

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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