Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Effects of probiotic and prebiotic supplements on serum inflamatory factors, tryptophan, cortisol, leptin and appetite in patients with major depressive disorder

Protocol summary

Summary

The aim of the current study is to investigate the effects of a bacterial formulation, which is effective on hypothalamus-hypophysis axis, and a prebiotic, which enhances the growth of thses bactrial strains (galactooligsaccharide), on depression and appetite score. Inclusion crateria: Melancolic type of major depression with mild to moderate level; consumption of one the fallowing anti-depressant drugs: sertraline, fluoxetine and citalopram; range for ages 18 to 50 years. Exlusion crateria: people who have consumed probiotic products regularly 2 month before the intervention; Omega 3 and anti-oxidant supplements consumption 4-6 weeks befor the beginning of intervention and following a specific diet. The sample size of the study is 90. The participants randomly allocate into three groups. Each group intakes one of the following intervention for two months: probiotic supplement (containing Lactobacillus helveticus, Bifidobacterium longum), prebiotic supplement and placebo. The following outcomes will be measured: serum levels of free leptin, tryptophan, inflammatory factors (IL-6, IL_1β and TNF-α), fasting urinary level of cortisol, appetite and depression score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092924271N1**
Registration date: **2015-11-29, 1394/09/08**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-11-29, 1394/09/08

Registrant information

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Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-06-19, 1395/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of probiotic and prebiotic supplements on serum inflamatory factors, tryptophan, cortisol, leptin and appetite in patients with major depressive disorder

Public title

Effects of probiotic and prebiotic supplements in patients with major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: range for ages 18 to 50 years; mild to

moderate melancholic type of major depression; intake of the following anti-depressant drugs: sertraline, fluoxetine and citalopram. Exclusion criteria: history of renal, hepatic, cardiovascular, respiratory diseases or food allergy; pregnancy and lactation; regular intake of probiotic less than 2 months before the beginning of the study; intake of the antioxidant or omega 3 supplements 6 weeks before the beginning of the study; alcohol intake; smoking cigarette (more than 5 Sticks during last 6 month) or tobacco (pipe and hookah at least one time during last month); any addiction to opiates; history of heart attack or stroke; following of specific diet; participation in another study during last two months; intake of drugs other than antidepressant drugs; allergy to the components of study supplements; any significant change in the diet and life style; any change in the drug regiment; inflammatory disease which last more than one week during the study; intake of antibiotics during the study.

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medicals Sciences

Street address
Tehran University of Medical Sciences, Qods St, Keshavarz Blvd

City
Tehran

Postal code

Approval date
2015-11-17, 1394/08/26

Ethics committee reference number
IR.TUMS.REC.1394.1190

Health conditions studied

1

Description of health condition studied
major depressive disoreders

ICD-10 code
F32

ICD-10 code description
Depressive episode

2

Description of health condition studied
Mild depression

ICD-10 code
F32.0

ICD-10 code description
Mild depressive episode

3

Description of health condition studied
Moderate depression

ICD-10 code
F32.1

ICD-10 code description
Moderate depressive episode

Primary outcomes

1

Description
serum free leptin

Timepoint
before and after the intervention

Method of measurement
serum level will be measured with sensetive ELISA

2

Description
TNF-α

Timepoint
before and after the intervention

Method of measurement
serum level will be measured with ELISA

3

Description
IL_1β

Timepoint
before and after the intervention

Method of measurement
serum level will be measured with ELISA

4

Description
IL-6

Timepoint

before and after the intervention

Method of measurement

serum level will be measured with ELISA

5

Description

tryptophane

Timepoint

before and after the intervention

Method of measurement

serum level will be measured with HPLC

6

Description

cortisol

Timepoint

before and after the intervention

Method of measurement

mass specterometry will be used for measuring urinary level of cortisol

7

Description

depression

Timepoint

before and after the intervention

Method of measurement

Beck questionaire

8

Description

appetite score

Timepoint

before and after the intervention

Method of measurement

visual analogue scale questionaire

Secondary outcomes

1

Description

weight

Timepoint

before and after the intervention

Method of measurement

Weighing scale

2

Description

energy intake

Timepoint

before and after the intervention

Method of measurement

24-hour recall

3

Description

physical activity

Timepoint

before and after the intervention

Method of measurement

IPAQ questionnaire

4

Description

height

Timepoint

before and after the intervention

Method of measurement

height scale

Intervention groups

1

Description

Probiotic supplement 5gr/day after launch for 2 month. The supplement contains: lactobacillus helveticus R0052, bifidobacterium longum R0175

Category

Treatment - Drugs

2

Description

Prebiotic supplement (galacto-oligosaccharide) 4.8 gr/day after the launch for 2 month (6 gr galacto-oligosaccharide powder with 80% purity)

Category

Treatment - Drugs

3

Description

Placebo/ 6 gr/ day malto dexestrine, after the launch

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

psychiatrist clinic

Full name of responsible person

Asma Kazemi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Masud Yunesian

Street address
Department of Environmental Health Engineering, School of Public Health

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Nutrition and dietetic school, Tehran University of medical Scienes

Full name of responsible person
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Position
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Other areas of specialty/work

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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