# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**


**Name**

Asma Kazemi

**Name of organization / entity**

Tehran University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 8895 5975

**Email address**

kazemias@razi.tums.ac.ir


**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**

Asma Kazemi

**Position**

Ph.D student in nutrition

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*