Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Effect of probiotic supplement on depression severity, plasma BDNF (brain drived neurotrophic factor), Cortisol & ACTH (adernocorticotropic hormon) in major depressive disorder patient

Protocol summary

Summary

The aim of this study is to determine the effect of probiotic capsule supplementation on depression severity, plasma BDNF (brain drived neurotrophic factor), Cortisol & ACTH (adernocorticotropic hormon) in major depressive disorder patient under treatment with fluoxetine. Study design: Randomized double-blinded controlled clinical trial. Inclusion Criteria: Patients with major depressive according to DSM-IV-TR criteria that they have not use any supplement and antidepressant drug at least 2 months prior to the start of the project, 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 the start of the project, psychosis, any type of severe chronic physical illness and any extreme and severe mental disorders (suicidal ideation, psychotic symptoms, symptoms of manic phase, etc) will be excluded. Population and sample size: 40 patients with major depressive disorder of eligible and referred to Roozbeh hospital to Tehran University of Medical Sciences, Tehran, Iran in the study will be selected. Intervention: Patients will be assigned to receive either the probiotic capsule (intervention group: n=20) or placebo capsule (control group: n=20). Blood samples will be taken at baseline and after 8-wk intervention. Intervention: 8 weeks. Outcomes: Depression sivierity will be measured at the beginning, end of forth week and end of the intervention; plasma BDNF and ACTH, and serum cortisol will be measured at the beginning and end of the intervention too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601102394N20**

Registration date: **2016-03-05, 1394/12/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-05, 1394/12/15

Registrant information

Name

Shima Jazayeri

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Center of Iran University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotic supplement on depression severity, plasma BDNF (brain drived neurotrophic factor), Cortisol

& ACTH (adernocorticotropic hormon) in major depressive disorder patient

Public title
The effect of probiotic supplement on depression severity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Patients with major depressive according to DSM-IV-TR criteria that they have not use any supplement and antidepressant drug at least 2 months prior to the start of the project; 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 the start of the project; psychosis; any type of severe chronic physical illness and any extreme and severe mental disorders (suicidal ideation, psychotic symptoms, symptoms of manic phase, etc)
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
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
Research Center of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, next to the Milad Hospital, between the intersection of Sheikh Fazlollah noori and Chamran, Hemmat Highway
City
Tehran
Postal code
1449614535
Approval date
2015-12-09, 1394/09/18
Ethics committee reference number
IR.IUMS.REC.1394.26635

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F32
ICD-10 code description
Depressive episode

Primary outcomes

1

Description
depression severity
Timepoint
begining, end of forth week, end of intervention
Method of measurement
Hamilton Depression Rating Scale

2

Description
BDNF
Timepoint
begining, end of intervention
Method of measurement
ELIZA

3

Description
cortisol
Timepoint
begining, end of intervention
Method of measurement
ELIZA

4

Description
ACTH
Timepoint
begining, end of intervention
Method of measurement
electrocemiLuminescence

Secondary outcomes

1

Description
side effect
Timepoint
end of forth week, end of intervention

Method of measurement
side effect questionnaire

2

Description
energy intake
Timepoint
begining, end of intervention
Method of measurement
24-hour recall

3

Description
physical activity
Timepoint
begining, end of intervention
Method of measurement
IPAQ questionnaire

Intervention groups

1

Description
Control, Placebo
Category
Placebo

2

Description
Intervention, Multi species probiotic capsules containing Lactobacillus helveticus, Bifidbacterium longum
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Hospital
Full name of responsible person
Vajihe Elahinejad
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Center of Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Javad Moosavi
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City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Center of 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
Iran University of Medical Sciences
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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