

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

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

& ACTH (adrenocorticotrophic 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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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

Full name of responsible person

Dr. Shima Jazayeri

Position

Ph.D. (Nutrition)

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Full name of responsible person Vajihe Elahinejad
Position Nutrition graduate student
Other areas of specialty/work
Street address
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Phone

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