

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of probiotics on BDNF, neuropeptide y plasma and serum HS-CRP in patients with generalized anxiety disorder

Protocol summary

Study aim

The aim of this study was to determine the effect of probiotic supplementation on serum BDNF, plasma neuropeptide, and HS-CRP in patients with generalized anxiety disorder

Design

double blind randomized controlled trial

Settings and conduct

Fifty patients with generalized anxiety will be referred from Ziaeiian Clinic. They will be randomly allocated to receive daily either probiotic supplement or placebo for 8 weeks. To measure BDNF, plasma neuropeptideY and HS-CRP, 10 ml of serum venous blood are collected after 10-12 hours of fasting at the beginning and at the end of the study.

Participants/Inclusion and exclusion criteria

Participants: patients with generalized anxiety disorder aged 18-65 years, Exclusion criteria: Having any illness including liver disease, kidney disease, diabetes, immune deficiency, etc, Having psychological illnesses including psychosis, Suicidal ideation, bipolar disorder and major depression, taking any medication in the previous 1 month, taking any medication related to psychiatric diseases including antidepressants, antipsychotics (maximum twice a week) and antibiotics in the previous 1 month

Intervention groups

intervention group: received daily (after lunch) a 220 mg capsule of probiotic containing (109 × 18 CFU) + sertraline control group: sertraline plus placebo capsule contains 220 mg starch, daily, after lunch for 8 weeks

Main outcome variables

BDNF, neuropeptideY, hs-crp

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090901002394N39**

Registration date: **2018-10-26, 1397/08/04**

Registration timing: **retrospective**

Last update: **2018-10-26, 1397/08/04**

Update count: **0**

Registration date

2018-10-26, 1397/08/04

Registrant information

Name

Shima Jazayeri

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotics on BDNF, neuropeptide y plasma and serum HS-CRP in patients with generalized anxiety disorder

Public title

Effects of probiotic in generalized anxiety disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

DSM-V diagnosed of GAD Adults between 18 and 65 years old Willing to participate.

Exclusion criteria:

Having illness including liver disease and kidney disease, diabetes, immune deficiency, etc Having psychological illnesses including psychosis, Suicidal ideation, bipolar disorder and major depression People who are expected to have limited partnerships such as forgetfulness and pregnancy Taking any medication in the previous 1 month Taking any medication related to psychiatric diseases including antidepressants, antipsychotics, etc. (maximum of two times per week) and antibiotics in the previous 1 month Taking any supplement including probiotic supplement, fiber, prebiotics, omega-3, vitamins and minerals in the previous 1 month; Consumption of fermented foods (except yogurt), such as sour cream, acidophilus milk, kefir and some cheeses such as blue vein cheese or Swiss cheese in the previous 1 month substance abuse The compliance less than 80%.

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: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects divided into two groups: intervention and placebo (stratified randomization)Based on age(18-40 40-65) Use 4-way permutation blocks and select blocks based on random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Probiotic and placebo supplementation is similar in all respects and is encoded by a third person not aware of the contents of the cans and randomly divided into two groups of patients. None of the patients and the investigator will be aware of the group in which the patients are located.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences,Hemmat Highway, Tehran, Iran

City

Tehran

Province

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Postal code

1449614535

Approval date

2017-05-03, 1396/02/13

Ethics committee reference number

IR.IUMS.REC 1396.9413468002

Health conditions studied

1

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Anxiety that is generalized and persistent but not restricted to, or even strongly predominating in, any particular environmental circumstances (i.e. it is "free-floating"). The dominant symptoms are variable but include complaints of persistent nervousness

Primary outcomes

1

Description

BDNF

Timepoint

At baseline, after 2 month

Method of measurement

Blood test

2

Description

hs-crp

Timepoint

At baseline, after 2 month

Method of measurement

Blood test

3

Description

Neuropeptide y

Timepoint

At baseline, after 2 month
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: sertraline plus probiotic supplement
Contain Bifidobacterium Longom, Bifidobacterium
bifidum, Bifidobacterium lactis, Lactobacillus
acidophilus(18×10⁹ CFU) and small amounts of
fructooligosaccharides (a contributor to the growth and
activity of microorganisms) daily after lunch for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: sertraline plus placebo capsule contains
220 mg starch, daily, after lunch for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Ziaeian Hospital

Full name of responsible person

Dr. Mohamad Effatpanah

Street address

Gazvin Sreet, Abouzar St, Clinic of Ziaeian Hospita

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mahnaz Reisian

Position

Master student in nutrition sciences

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Name of organization / entity

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Full name of responsible person

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Position

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Ph.D.

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

There is no more information.

When the data will become available and for how long

There is no more information.

To whom data/document is available

There is no more information.

Under which criteria data/document could be used

There is no more information.

From where data/document is obtainable

There is no more information.

What processes are involved for a request to access data/document

There is no more information.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

mahnazreisian

Position

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Latest degree

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Other areas of specialty/work

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