Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 neopeptide, 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 Ziaeian 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

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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
Tehran
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 disorde
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 nervousne

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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Person responsible for updating data

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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