Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Effects of consumption of probiotic on symptom severity , quality of life, plasma ACTH and serum cortisol in patients with generalized anxiety disorder

Protocol summary

Summary

Objectives: The aim of this study is to determine effects of probiotic on symptom severity, quality of life, plasma ACTH and serum cortisol in patients with generalized anxiety disorder. 2- Design: double blind randomized controlled trial 3- Setting 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. Symptom severity of Anxiety will be assessed by Beck Anxiety Inventory, Scale for anxiety and State-Trait Anxiety Inventory questionnaires and quality of life will be assessed by World health organization Quality of Life Questionnaire, in week 0, 4 and 8. For measurement of plasma ACTH and serum cortisol,ten milliliters of venous fasting blood sample will be collected at baseline and after intervention. 4- 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. 5- Intervention: probiotic (18×109 CFU) or placebo daily for 8 weeks 6- Main outcome measures variables: Symptom severity, plasma ACTH, serum cortisol and quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612072394N35**
Registration date: **2017-03-04, 1395/12/14**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-03-04, 1395/12/14

Registrant information

Name
Shima Jazayeri
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8670 4805
Email address
sjazayeri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of consumption of probiotic on symptom severity , quality of life, plasma ACTH and serum cortisol 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

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Ethics committee of Iran University of Medical Sciences

Street address

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

City

Tehran

Postal code

Approval date

2016-11-19, 1395/08/29

Ethics committee reference number

IR.IUMS.REC 1395.9411468002

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 nervousne

Primary outcomes

1

Description

Symptom severity

Timepoint

at baseline, after 1 month and after 2 month

Method of measurement

Beck Anxiety Inventory, Hamilton Rating Scale for anxiety and State-Trait Anxiety Inventory questionnaires

2

Description

plasma acth

Timepoint

at baseline, after 1 month and after 2 month

Method of measurement

Electro-chemiluminescence immunoassay

3

Description

serum cortisol

Timepoint

at baseline, after 1 month and after 2 month

Method of measurement

Chemiluminescence immunoassay

4

Description

quality of life

Timepoint

at baseline, after 1 month and after 2 month

Method of measurement

quality of life, world health organization questionnaire

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 Hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Dr.Seyed Ali Javad Moosavi
Street address
Iran university of medical sciences,Hemmat Highway,Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for research, 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
Sevda Eskandrazadeh
Position
Master student in nutrition sciences
Other areas of specialty/work
Street address
School of public health, Iran university of medical sciences,Hemmat Highway,Tehran, Iran
City
Tehran
Postal code
Phone
+98 912 072 8106
Fax
Email
sevda_eskandarzadeh@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Shima Jazayeri
Position
p.h.d (nutrition)
Other areas of specialty/work
Street address
School of public health, Iran university of medical sciences,Hemmat Highway,Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 8670 4805
Fax
Email
jazayeri.sh@iums.ac.ir
Web page address

Person responsible for updating data

Contact

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