

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 Ziaeiian 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 (18x10⁹ 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

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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 nervousness

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

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Person responsible for scientific inquiries

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Position

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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