Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effects of probiotics on general mental health in healthy human volunteers of Shahrood city

Protocol summary

Summary

The aim of this study: Evaluation of the effects of probiotics on general mental health in healthy human volunteers of Shahrood city. Study design: After explaining the purpose of the study and obtaining the informed consent, people will be allocated into A and B groups. The study is double blind, single-center, phase 3 trial. Inclusion criteria: Informed consent. Exclusion criteria: Diabetes; cardiovascular diseases; gastrointestinal diseases; routine use of probiotics. Sample size: 50 people are participated in the study with 25 people in each group. Intervention group: Familact probiotic capsule 10 milion unit oral. Control group: Starch capsule 3 gram oral. Primary outcome: Improve general mental health.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017053034246N1**
Registration date: **2017-10-10, 1396/07/18**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-10-10, 1396/07/18

Registrant information

Name
Hadi Sasani
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Islamic Azad University Of Shahrood
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-10-22, 1396/07/30

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of probiotics on general mental health in healthy human volunteers of Shahrood city

Public title

Effect of probiotics on general mental health in healthy human volunteers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Informed consent Exclusion criteria: Diabetes; cardiovascular diseases; gastrointestinal diseases; routine use of probiotics

Age

From **21 years** old to **50 years** old

Gender

Both

Phase

3

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 Islamic Azad University of Shahrood

Street address

Islamic Azad University of Shahrood, Tehran Blvd, Shahrood City

City

Shahrood

Postal code

Approval date

2016-11-10, 1395/08/20

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1395.7

Health conditions studied

1

Description of health condition studied

General mental health

ICD-10 code

R46.8

ICD-10 code description

Other symptoms and signs involving appearance and behaviour

2

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

General mental health

Timepoint

Before intervention and one day after intervention

Method of measurement

Goldberg's general mental health questionnaire

Secondary outcomes

1

Description

Generelized anxiety disorder

Timepoint

One day before intervention, on day after intervention

Method of measurement

Goldberg's general mental health questionnaire

Intervention groups

1

Description

Intervention: Single dose of 10 million unit familact probiotic capsule after breakfast 28 days

Category

Treatment - Drugs

2

Description

Control: Single dose of 3 gram placebo starch capsule after breakfast 28 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Alanbia Hospital of Shahrood

Full name of responsible person

Fatemeh Amirkhlili

Street address

Khatam Alanbia Hospital of Shahrood, Tehran Blvd, Shahrood

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology

Full name of responsible person

Sahebali Manafi

Street address

Islamic Azad University of Shahrood, Tehran Blvd,

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City

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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

Vice chancellor for Research and Technology

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

Islamic Azad University of Shahrood

Full name of responsible person

Hadi Sasani

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Medical Student

Other areas of specialty/work

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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