

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation of the clinical effects of probiotics in social anxiety disorder of medical students of Shahrood city

Protocol summary

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Summary

The aim of this study: Evaluation of the clinical effects of probiotics in social anxiety disorder of medical students of Shahrood city. Study design: After explaining the purpose of the study and obtaining the informed consent, patients will be allocated into A and B groups. The study is double blind, single-center, phase 3 trial. Inclusion criteria: Medical students of Shahrood city. Exclusion criteria: Documented liver or renal diseases; Routine use of probiotics. Sample size: 40 patients are participated in the study with 20 patients in each group. Intervention group: familact capsule 10 million unit. Control group: starch capsule 3 gram. Primary outcome: decrease of social anxiety disorder.

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-10-22, 1396/07/30

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017053034245N1**

Registration date: **2017-10-11, 1396/07/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-11, 1396/07/19

Registrant information

Name

Farhad Honarvar

Name of organization / entity

Islamic Azad University of Shahrood.

Country

Iran (Islamic Republic of)

Phone

+98 23 3223 3546

Email address

Scientific title

Evaluation of the clinical effects of probiotics in social anxiety disorder of medical students of Shahrood city

Public title

The effect of probiotics in social phobia of medical students

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Medical students of Shahrood city

Exclusion criteria: Documented liver or renal diseases;

Routine use of probiotics

Age

From **20 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Shahrood

Postal code

Approval date

2016-11-10, 1395/08/20

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1395.6

Health conditions studied

1

Description of health condition studied

Social Phobia

ICD-10 code

F40.1

ICD-10 code description

Social phobias

Primary outcomes

1

Description

Social phobia disorder

Timepoint

First day of intervention and two days after the end of the intervention

Method of measurement

Conver's social phobia questionnaire

Secondary outcomes

1

Description

Depression

Timepoint

First day of intervention and two days after the end of intervention

Method of measurement

Beck's depression questionnaire

Intervention groups

1

Description

Intervention: Single dose of 10 milion CFU per each ML Familact probiotic capsule one hour after breakfast during 28 days

Category

Treatment - Drugs

2

Description

Control group: Single dose of 3 gram starch capsule one hour after breakfast during 28 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical School of Islamic Azad University Of Shahrood

Full name of responsible person

Fatemeh Amirkhalili

Street address

Medical School of Islamic Azad University Of Shahrood, Tehran Blvd, Shahrood

City

Shahrood

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology, Islamic Azad University of Shahrood

Full name of responsible person

Sahebali Manafi

Street address

21,Shahrdari street,Farhangian towndown,Shahrood City

City

Shahrood

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, Islamic Azad University of Shahrood

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

Farhad Honarvar

Position

Medical Student

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Web page address**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