Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Gut Microbiome Composition and Response to Probiotic Intervention in Patients with Fibromyalgia using a Neurobiological Approach

Protocol summary

Study aim

Investigate the effect of probiotic supplementation on pain,sleep ,intestinal composition in patients with Fibromyalgia.

Design

Present study was designed in two phases : in this phase , the composition of intestinal microbiome and biomarkers - inflammatory markers in female patients with Fibromyalgia (based on ACR-2016) were compared with healthy group matche in terms of age and body mass index (BMI). Blood and feces samples from both groups are collected and analyzed to identify disbiosispatterns and inflammatory markers. in the second phase (double - blind clinical trial) , the patient participants were randomly divided into two intervention groups (receiving probiotic lactobacillus rhamnosus and Bifidobacterium longum) and control group (placebo) for 8 weeks .in both groups ,blood and feces samples were collected in two times (before and after the intervention) . Severity of pain , sleep quality , and mental status were assessed with the standard questionnaires (vas , BPI , HADS , and PSQI) at both times .also , the levels of inflammatory cytokines (Il - 6 ,TNF- α, CRP, bdnf) and intestinal metabolites (SCFA) will be measured .

Settings and conduct

Imam khomeini hospital complex

Participants/Inclusion and exclusion criteria

Patients : women aged 55 - 18 (based on acr - 2016 criteria) . Controls (case - control part) : healthy women , age and BMI

Intervention groups

* daily intake of a probiotic capsule containing : - Lactobacillus rhamnosus (10 cfu) - Bifidobacterium longum (10 cfu) Time : 8 weeks

Main outcome variables

1. Pain intensity 2. Sleep quality 3. Gut microbiome composition 4. Levels of inflammatory markers (IL-6, TNF-α, CRP) 5. Gut metabolites (short-chain fatty acids)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260315068995N1**
Registration date: **2026-04-13, 1405/01/24**
Registration timing: **prospective**

Last update: **2026-04-13, 1405/01/24**
Update count: **0**

Registration date

2026-04-13, 1405/01/24

Registrant information

Name

Sepideh Khodaparast

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6658 1560

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2027-05-21, 1406/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Gut Microbiome Composition and Response to Probiotic Intervention in Patients with Fibromyalgia using a Neurobiological Approach

Public title

Gut Microbiome Composition and Response to Probiotic Intervention in Patients with Fibromyalgia using a Neurobiological Approach

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of فیبرومیالژیا based on acr - 2016 . Participate and sign the consent form . Antibiotic or probiotic consumption in the past four weeks Lack of inflammatory bowel disease or severe psychiatric disorders .

Exclusion criteria:

Pregnancy or lactation .history of gi tract surgery . Consumption of immunosuppressive drugs . Lack of adherence to intervention or withdrawal during the study .

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

1.Details of the Randomization Process: In this study, randomization is performed by allocating patients to intervention and control groups using random blocks in a 1:1 ratio. This method ensures that the distribution of patients in each group is random and unbiased. 2.Linguistic Consistency on Both Sides: In the design and reporting of this study, all terms and expressions have been applied consistently and harmoniously on both sides to ensure that there is no ambiguity in the interpretation of the results. 3.Randomization Method: In this study, the randomization method is precisely determined by allocating patients using random blocks and implementing double blinding (so that both patients and researchers are unaware of group assignments). Additionally, the supplements are coded and packaged by an independent individual to prevent any bias.

Blinding (investigator's opinion)

Double blinded

Blinding description

Description of the Blinding Method: In this study, double blinding is fully implemented. This means that both patients and researchers will be unaware of group assignments. Patients are randomly allocated to the intervention and control groups, and all information related to the groups is managed in a coded manner by an independent individual. This person is responsible for the packaging and distribution of the supplements, ensuring that they have no knowledge of the type of intervention the patients receive. This approach ensures that there is no bias in the assessment of the results. Linguistic Consistency on Both Sides: All terms and expressions have been used consistently and harmoniously on both sides (Persian and English) to ensure that there is no ambiguity in the interpretation of the findings.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz Blvd. Tehran, Iran

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Tehran

Province

Tehran

Postal code

1419733141

Approval date

2025-12-18, 1404/09/27

Ethics committee reference number

IR.TUMS.IKHC.REC.1404.398

Health conditions studied

1

Description of health condition studied

Fibromyalgia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Receive or receive probiotic capsules as an intervention

Timepoint

8 weeks

Method of measurement

Recording the intervention or control group (placebo)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In interventional phase , eligible patients were divided into two groups : intervention and control groups using randomized block design with 1 : 1 ratio .two - way کورسازی is done by the codification of supplements and the use of an independent individual to manage allocation .
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital complex
Full name of responsible person
Dr. Sepideh Khodaparast
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr. Sepideh Khodaparast
Position
Assistant Professor at Brain and spinal cord injury research Centre, Neuroscience Institute, Tehran
Latest degree
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Other areas of specialty/work
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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
I haven 't decided yet - the release schedule is not yet clear .
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
Undecided - It is not yet known if there will be 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