

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 matched in terms of age and body mass index (BMI). Blood and feces samples from both groups are collected and analyzed to identify dysbiosis patterns 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)

Phone

+98 21 6658 1560

Email address

skhodaparast@sina.tums.ac.ir

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	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Tehran University of Medical Sciences
Street address	Keshavarz Blvd. Tehran, Iran
City	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	
<u>1</u>	
Description of health condition studied	Fibromyalgia
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
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 کورساری 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

Street address

Tehran University of Medical Sciences (TUMS),
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skhodaparast@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ccenter of the medical research institute of tehran
university of medical sciences

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Tehran University of Medical Sciences (TUMS),
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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

Ph.D.

Other areas of specialty/work

Laboratory Medicine

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Person responsible for scientific 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

Ph.D.

Other areas of specialty/work

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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

Person responsible for updating data**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

Ph.D.

Other areas of specialty/work

Laboratory Medicine

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