Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The assessment of probiotics' effects on gastrointestinal inflammation and symptoms in patients with scleroderma

Protocol summary

Study aim
Probiotics' effects on gastrointestinal inflammation and symptoms in patients with Scleroderma

Design
A randomized, double-blind, parallel-group, phase 3 clinical trial was conducted on 44 patients with a control group. The randomization was performed using the rand function in Microsoft Excel software.

Settings and conduct
After the diagnosis of scleroderma by a rheumatologist, patients were randomly divided into two equal groups using block randomization. One group was prescribed a probiotic daily; the other group was prescribed a placebo. Patients who completed the entry and exit conditions of the study were placed under standard scleroderma treatment. The study was conducted at the Rheumatology Clinic of Imam Reza Hospital in Mashhad. Blinding was performed for the physician, patient, and evaluator.

Participants/Inclusion and exclusion criteria
Inclusion: Diagnosis of scleroderma based on ACR-Eular criteria Patients aged 20 to 65 years Scleroderma patients with malabsorption symptoms such as bloating, bowel dysfunction, cyclic constipation and diarrhea, heartburn If taking corticosteroids, they have not changed the dose of corticosteroids in the past month Exclusion: Pregnancy Breastfeeding Active infection New organ involvement IBS Malignancy IBD and ulcerative colitis Antibiotic intake in the past 2 weeks Probiotic, endoxan, rituximab, and biologic drugs intake in the past 4 weeks Medication changes in 2 month period of follow-up Overlap syndromes Voluntary withdrawal from the study

Intervention groups
In the intervention group, patients with scleroderma receive a probiotic tablet daily for 2 months. In the control group, patients receive a placebo drug.

Main outcome variables
IL-17, IL-4, IFN-δ, and IL-10 gastrointestinal symptoms, including reflux, bloating, fecal soiling, diarrhea, emotional and social function, and constipation, using the GIT 2.0 Score questionnaire.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240115060698N1**
Registration date: **2024-01-28, 1402/11/08**
Registration timing: **prospective**

Last update: **2024-01-28, 1402/11/08**
Update count: **0**

Registration date
2024-01-28, 1402/11/08

Registrant information

Name
Hossein Ghazaee

Name of organization / entity

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Iran (Islamic Republic of)

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+98 51 3604 2913

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ghazaeih971@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of probiotics' effects on gastrointestinal inflammation and symptoms in patients with scleroderma

Public title

Probiotic effect on scleroderma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of scleroderma based on ACR-Eular criteria Patients aged 20 to 65 years Scleroderma patients with malabsorption symptoms such as bloating, bowel dysfunction, cyclic constipation and diarrhea, heartburn If taking corticosteroids, they have not changed the dose of corticosteroids in the past month.

Exclusion criteria:

Pregnancy Breastfeeding Active infection New organ involvement Irritable bowel disease Malignancy Inflammatory bowel disease (IBD) and ulcerative colitis (UC) Antibiotic intake in past 2 weeks Probiotic intake in past 4 weeks Endoxan in past 4 weeks Rituximab in past 4 weeks Biologic drugs in past 4 weeks Medication changes in 2 month period of follow-up Overlap syndromes Voluntary withdrawal from the study

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization with 11 blocks of 4 will be performed. We will use Excel software and the (rand) function to prepare random orders. The steps to perform block randomization using Excel are: 1- Create a group column with A, A, B, B, C, C. 2- In another column: assign random numbers to each letter with =rand(). While doing this, use "paste values" to stop the random recalculation 3- Sort the random numbers from lowest to highest by selecting expansion of choice 4- Copy the group column and paste it into the sequence column 5- Repeat the above steps 11 times 6- Finish: save A unique numerical code will be assigned to each of the randomly generated sequences. The randomization will be done by the statistical consultant of the study and the information will only be available to the study colleague at the time of intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients and physicians evaluating the interventions designed in the study or the outcomes after performing the intervention (rheumatology assistant and rheumatologist) will not be informed of the group in which the patient under study is located. All interventions in both groups will be similarly designed and the process will be the same for all samples in all groups. The drugs used will also be supplied in similar shapes and packaging so that no one can identify the study group during the course of the study

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Central building of Mashhad university of medical science, next to Alton tower, Daneshgah street, Mashhad, Khorasan Razavi, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2023-09-18, 1402/06/27

Ethics committee reference number

IR.MUMS.IRH.REC.1402.150

Health conditions studied

1

Description of health condition studied

Scleroderma

ICD-10 code

M34

ICD-10 code description

Systemic sclerosis [scleroderma]

Primary outcomes

1

Description
Interferon delta
Timepoint
At the beginning of the study (before the intervention) and 2 months after starting probiotic consumption
Method of measurement
Blood sampling from the brachial vein with 5 cc of blood to prepare serum for ELISA test

2

Description
Interleukin 4
Timepoint
At the beginning of the study (before the intervention) and 2 months after starting probiotic consumption
Method of measurement
Blood sampling from the brachial vein with 5 cc of blood to prepare serum for ELISA test

3

Description
Interleukin 10
Timepoint
At the beginning of the study (before the intervention) and 2 months after starting probiotic consumption
Method of measurement
Blood sampling from the brachial vein with 5 cc of blood to prepare serum for ELISA test

4

Description
Interleukin 17
Timepoint
At the beginning of the study (before the intervention) and 2 months after starting probiotic consumption
Method of measurement
Blood sampling from the brachial vein with 5 cc of blood to prepare serum for ELISA test

5

Description
Reflux
Timepoint
At the beginning of the study (before the intervention) and 2 months after starting probiotic consumption
Method of measurement
The University of California Los Angeles Scleroderma Clinical Trials Consortium gastrointestinal tract 2.0 (UCLA GIT 2.0) questionnaire

6

Description
Distention/bloating
Timepoint
At the beginning of the study (before the intervention) and 2 months after starting probiotic consumption
Method of measurement
UCLA GIT 2.0 Questionnaire

7

Description
Fecal soilage
Timepoint
At the beginning of the study (before the intervention) and 2 months after starting probiotic consumption
Method of measurement
UCLA GIT 2.0 Questionnaire

8

Description
Diarrhea
Timepoint
At the beginning of the study (before the intervention) and 2 months after starting probiotic consumption
Method of measurement
UCLA GIT 2.0 Questionnaire

9

Description
Social functioning
Timepoint
At the beginning of the study (before the intervention) and 2 months after starting probiotic consumption
Method of measurement
UCLA GIT 2.0 Questionnaire

10

Description
Emotional well-being
Timepoint
At the beginning of the study (before the intervention) and 2 months after starting probiotic consumption
Method of measurement
UCLA GIT 2.0 Questionnaire

11

Description
Constipation
Timepoint
At the beginning of the study (before the intervention) and 2 months after starting probiotic consumption
Method of measurement
UCLA GIT 2.0 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: The probiotic capsule (LactoCare) and placebo are prepared by the Tehran Biotechnology

Company. The probiotic capsule is completely similar to the placebo in terms of shape, color, and size, and patients consume one capsule of the placebo daily for two months.

Category

Placebo

2

Description

Intervention group: The probiotic capsule (LactoCare) and placebo are prepared by the Tehran Biotechnology Company. Each LactoCare capsule contains 21 milligrams of Fructooligosaccharides (FOS). Patients receive one capsule daily for 2 months. This capsule contains 10^9^ CFU of Lactobacillus ruteri, Lactobacillus rhamnosus, and Bifidobacterium bacteria.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology clinic of Imam Reza hospital

Full name of responsible person

Zahra Mirfeizi

Street address

Imam Reza hospital, Imam Reza hospital square, Ebn Sina street, Mashhad, Khorasan Razavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

4012162

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hossein Ghazaee

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
Information related to the main purpose of the study and data related to it is available for sharing
When the data will become available and for how long
Starting accessibility 6 months after publication
To whom data/document is available
Researchers from universities and scientific institutions and people who are engaged in industry
Under which criteria data/document could be used
The data could be used in clinical and research intentions
From where data/document is obtainable
Dr. Zahra Mirfeizi, Rheumatologist mirfeiziz@mums.ac.ir professor in the internal medicine group of Imam Reza Hospital, Mashhad
What processes are involved for a request to access data/document
The applicant can send his/her request to Dr. Zahra Mirfeiziz at mirfeiziz@mums.ac.ir by email.
Comments