

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A clinical trial with the aim of investigating the multi-therapeutic effect of *Lactobacillus roteri*, *Lactobacillus rhamnosus* and *Bifidobacterium infantis* on IL-6 and TNF- α cytokines in patients with systemic lupus erythematosus

Protocol summary

Study aim

The effect of probiotics *Lactobacillus reuteri*, *Lactobacillus rhamnosus* and *Bifidobacterium infantis* on serum levels of IL-6 and TNF- α in patients with systemic lupus erythematosus

Design

Patients are divided into two equal groups using the randomization method (23 people in each group). In the treatment group, in addition to common treatments for systemic lupus erythematosus, three probiotics *Lactobacillus roteri*, *Lactobacillus rhamnosus*, and *Bifidobacterium* are consumed daily in a capsule, and in the other group, in addition to common treatments, placebo is consumed instead of three probiotics. The duration of the intervention is 2 months.

Settings and conduct

Before and after the intervention, 5 cc of blood will be collected from the patients' brachial veins to assess immunological responses; the serum is stored in the freezer at the Immunology Research Center of the Bo Ali Research Institute in Mashhad. In the immunology laboratory of North Khorasan Faculty of Medical Sciences, IL-6 and TNF-cytokines will be determined via the ELISA technique.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with mild to moderate systemic lupus erythematosus based on the SLEDAI score, aged 20 to 55 years. Exclusion criteria: Patients with no underlying disease, such as kidney transplant, or who receive immunosuppressive drugs unrelated to systemic lupus erythematosus.

Intervention groups

In the intervention group, in addition to common treatments for systemic lupus erythematosus, three probiotics *Lactobacillus roteri*, *Lactobacillus rhamnosus*, and *Bifidobacterium* are consumed daily in a capsule

Main outcome variables

Evaluation of interleukin 6 (IL-6) and Tumor necrosis Factor alpha (TNF- α) and Systemic Lupus Erythematosus Disease Activity (SLEDAI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191223045865N1**
Registration date: **2023-06-13, 1402/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-13, 1402/03/23**

Update count: **0**

Registration date

2023-06-13, 1402/03/23

Registrant information

Name

Mehdi Barati

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3845 0951

Email address

baraticm961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-20, 1402/02/30

Expected recruitment end date

2024-05-19, 1403/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A clinical trial with the aim of investigating the multi-therapeutic effect of Lactobacillus roteri, Lactobacillus rhamnosus and Bifidobacterium infantis on IL-6 and TNF-α cytokines in patients with systemic lupus erythematosus

Public title
The effect of probiotics on lupus

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Men and women with mild to moderate systemic lupus erythematosus based on Systemic Lupus Erythematosus Disease Activity Index score
Exclusion criteria:
The patient did not receive antibacterial medication at the time of the study Patients with lupus and no underlying disease such as kidney transplant who receive immunosuppressive drugs other than systemic lupus erythematosus for any reason.

Age
From **20 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **23**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization: In this study, Block Randomization method with 13 blocks size 4 will be used. We will use Excel software and function (rand) to prepare random sequences. The steps of doing randomization using Excel: 1. Make a column group with A,A,B,B,C,C 2. In another column: =rand(). Assign random numbers to each letter. While doing this, use "paste values" to stop recalculating the randomization. =rand() 3. Sorting. Sort the random numbers from the lowest to the highest with selecting expand selection. 4. Sequence. Copy group column and paste it in sequence. 5. Repeat above steps 11 times And a repeat with block size 2. 6. Finish. Save the record. Concealment: A specific numerical code will

be assigned to each of the randomly created sequences. Randomization will be done by the study epidemiologist and information will be only given to a study staff at the time of initiation of the intervention.

Blinding (investigator's opinion)
Triple blinded

Blinding description
This study is a double-blind randomized clinical trial, in other words, in this study, the researcher and the patient do not know the type of drug used (probiotic and placebo). In this study, drugs are sent in two separate boxes with codes A and B. The nature of the boxes will be reported only after taking the drug and collecting clinical and laboratory data.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of North Khorasan University of Medical Sciences
Street address
Dolat Blvd
City
Bojnourd
Province
North Khorasan
Postal code
74877-94149

Approval date
2023-05-06, 1402/02/16

Ethics committee reference number
IR.NKUMS.REC.1402.009

Health conditions studied

1

Description of health condition studied
Systemic lupus erythematosus (SLE)

ICD-10 code
M32

ICD-10 code description
Systemic lupus erythematosus (SLE)

Primary outcomes

1

Description
Interleukin 6

Timepoint

In this study, blood is taken from the patient before starting the treatment, and then treatment with probiotics is started. Probiotic treatment is done for two months, and then blood is taken from the patient once again and interleukin 6 is measured.

Method of measurement

ELISA

2

Description

TNF-a cytokines

Timepoint

In this study, blood is taken from the patient before starting the treatment, and then treatment with probiotics is started. Probiotic treatment is done for two months, and then blood is taken from the patient once again and TNF alpha is measured.

Method of measurement

ELISA

3

Description

Systemic Lupus Erythematosus Disease Activity Index (SLEDAI)

Timepoint

In this study, before the start of the treatment, blood is taken from the patient and the SLE disease activity index (SLAEDAI) questionnaire is completed, and then the treatment with probiotics is started, probiotic treatment is carried out for two months, and then the SLEDAI questionnaire is completed once again.

Method of measurement

Questionnaire SELDAI K2000

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to common treatments for systemic lupus erythematosus, this group is given three probiotics *Lactobacillus roteri*, *Lactobacillus rhamnosus* and *Bifidobacterium* in a capsule daily. The duration of the intervention is 2 months.

Category

Treatment - Drugs

2

Description

Control group: In addition to common treatments for systemic lupus erythematosus, this group instead of probiotics placebo is given in a capsule daily. The duration of the intervention is 2 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

NorthKhorasan University of Medical Sciences

Full name of responsible person

Mehdi Barati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Bahram Bibak

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Dolat Blvd., Central Building of North Khorasan University of Medical Sciences, Bojnourd

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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

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Mehdi Barati

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries

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Position

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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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data will be shared, including the amount of medication, duration of medication use, and all outcomes.

When the data will become available and for how long

All data will be published after the study is done

To whom data/document is available

Data will be made available to all researchers upon request

Under which criteria data/document could be used

Analyzed data and clinical results of treatment effect in patients are accessible

From where data/document is obtainable

Clinical trial registrar

What processes are involved for a request to access data/document

Request from the trial registrar by email

Comments