Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

Study aim
The effect of probiotics Lactobacillus reuteri, Lactobacillus rhamnosus and Bifidobacterium infanti 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

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Iran (Islamic Republic of)

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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 infante on IL-6 and TNF-a 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 indedx (SLAEDAI) questionnaire is completed, and then the treatment with pobiotics 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
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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
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 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