Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluate the effect of probiotics on the improvement of autoimmune inflammation in patients with systemic lupus erythematosus

Protocol summary

Study aim
Evaluation of probiotic administration on immune responses and clinical manifestations in patients with systemic lupus erythematosus

Design
Clinical trial with control group, community-based, with parallel groups, thriple blind, randomized

Settings and conduct
Before and 4 months after the intervention, 5 cc of blood is taken from the brachial vein of patients for examinations, real time PCR and preparation of serum for ELISA test.In monthly visits, in addition to the activity of the disease, a checklist of the number and dose of drugs used by patients in both groups is recorded to be compared at the end of the study and the confusing points of treatment changes are removed from the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients with systemic lupus erythematosus between the ages of 18 to 45 years living in Mashhad and surrounding cities with a SLEDAI score between 4.5 to 10.Be willing to cooperate in the project.
Exclusion criteria: Patients who are not satisfied to continue cooperation.

Intervention groups
Patients are divided into two equal groups (23 people in each group) using block block randomization method and in one group, in addition to common treatments for lupus, oral probiotic Lact 2 Plus is prescribed, and in the other group, in addition to common treatments, A placebo is prescribed.

Main outcome variables
Evaluation of IL17 protein levels, Evaluation of FOXP3, T-bet, GATA-3 and ROR γt transcription factor gene expression by SYBR Green real-time RT-PCR at the beginning of the process, four months after the course

General information

Reason for update

Acronym
SLE(systemic lupus erythematosus)

IRCT registration information
IRCT registration number: **IRCT20201019049073N1**
Registration date: **2021-01-08, 1399/10/19**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-08, 1399/10/19**
Update count: **0**

Registration date
2021-01-08, 1399/10/19

Registrant information

Name
Arezoo Faridzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3802 2229

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faridzadeha961@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-28, 1399/08/07

Expected recruitment end date
2022-12-10, 1401/09/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluate the effect of probiotics on the improvement of autoimmune inflammation in patients with systemic lupus erythematosus

Public title
Evaluate of effect probiotic on treatment of systemic lupus erythematosus

Purpose
Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with SLE have a SLEDAI score of 4.5 to 10. Patients should be between 18 and 45 years old. Patients are willing to cooperate in the project.

Exclusion criteria:
Patients will be excluded from the study if there is a change in the dose or number of medications taken by patients.

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
Method of block randomization Unit of randomization individual Tools used in randomization computer software The type of randomization in this study is simple random sampling. To select the participants in this study, 50 patients from whom the diagnosis of lupus has been confirmed are randomly included in the study. Then 25 patients are randomly divided into probiotic group and 25 patients into placebo group.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participants will receive the same drug or placebo. The main researcher is unaware of the effect of the drug on improving quality of life and effective immune responses.

Placebo
Used

Assignment
Parallel

Other design features
Our review of past studies showed that no similar studies have been conducted in this area.Therefore, this study can provide new results on the effect of probiotics on systemic lupus erythematosus disease.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mshhad University of medical Sciences

Street address
Ferdowsi University of Medical Sciences , Azadi Sq, Mashhad-Iran

City
mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2020-12-28, 1399/10/08

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.577

Health conditions studied

1

Description of health condition studied
SLE(Systemic lupus erythematosus)

ICD-10 code

ICD-10 code description
kinds of autoimmune diseases

Primary outcomes

1

Description
IL17, Evaluation of FOXP3, T-bet, GATA-3 and ROR γt transcription factor gene expression by SYBR Green real-time RT-PCR method

Timepoint
Before intervention, 4 months after intervention

Method of measurement
Elisa test, SYBR Green real-time RT-PCR

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to common therapies, one oral probiotic FamiLact 2plus daily includes the strains of Lactobacillus acidophilus, Lactobacillus casei, Lactobacillus rhamnosus, Lactobacillus salivarius, Lactobacillus reuteri, Bifidobacterium lactis, Bifidobacterium longum, Bifidobacterium bifidum. The duration of the intervention is 4 months. FamiLact 2Plus is from Zist Takhmir Company, made in Iran.

Category
Treatment - Drugs

2

Description
Control group: In addition to common treatments, one placebo is given daily.The duration of the intervention is 4 months. The placebo is from Zist Takhmir Company, made in Iran.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Doctor Seyedeh Zahra Mirfeizi
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Rheumatology Research Center of Imam Reza, mashhad city Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Doctor Mohsen Tafaghodi
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faculty of medical, Mashhad Ferdowsi University, Ferdowsi square, Mashhad city
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Grant name
Mashhad University of Medical Sciences
Grant code / Reference number
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
Arezoo Faridzadeh
Position
MD-Ph.D candidate
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)
Undecided - It is not yet known if there will be a plan to make this available
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