Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Investigating the effect of metformin on disease activity in systemic lupus erythematosus

Protocol summary

Study aim
Investigating the effect of metformin on disease activity in systemic lupus erythematosus

Design
This clinical trial has an intervention group of 32 people and a control group of 32 people. Randomization and blinding are not done in this study. Its phase is 2-3. The sample size is 64 patients

Settings and conduct
Patients with systemic lupus erythematosus, eligible to enter the study, referred to the rheumatology clinic of Golestan Ahvaz Hospital, were visited by a rheumatology subspecialist, and then a questionnaire form was completed based on the SLEDAI table, which includes physical examinations and patient tests, and based on that, the SLE DAI score was calculated. These tests and examinations are repeated three months later.

Participants/Inclusion and exclusion criteria
64 patients suffering from systemic lupus erythematosus over the age of 18 will be included in the study and will be excluded from the study if they have involvement of the kidneys, central nervous system, heart failure, liver failure, pregnancy, breastfeeding, history of alcohol consumption and metformin use due to Diabetes mellitus.

Intervention groups
The intervention group consisted of 32 eligible patients with systemic lupus erythematosus, who received 500 mg metformin tablets every 8 hours in addition to taking the routine drugs of this disease. The control group, 32 eligible patients with systemic lupus erythematosus, who take routine drugs for this disease and do not receive metformin.

Main outcome variables
SLE DAI; arthritis; skin rash; hair loss; mucosal ulcer; fever, pleurisy; pericarditis; platelets; White blood cell; Complements (C3, C4, CH50); Anti-dS DNA, ESR

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220817055730N1**
Registration date: **2022-10-08, 1401/07/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-08, 1401/07/16**
Update count: **0**

Registration date
2022-10-08, 1401/07/16

Registrant information

Name
Sepideh Sehhat

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3235 6981

Email address
sehhat.s@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-18, 1401/06/27

Expected recruitment end date
2022-10-19, 1401/07/27

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of metformin on disease activity in systemic lupus erythematosus

Public title
Investigating the effect of metformin on the activity of systemic lupus erythematosus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
suffering from Systemic lupus erythematosus disease
Age above 18 years
Exclusion criteria:
Kidneys involvement Central Nervous System involvement Heart failure Hepatic failure pregnancy Breast feeding Alcohol consumption Metformin use due to Diabetes mellitus
Age
From **19 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features
64 eligible patients with systemic lupus erythematosus are randomly divided into two groups of 32 people. Metformin is given to one group and not to the control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences ,Golestan Hospital
Street address
Golestan blvd/Golestan Hospital/ Ahvaz Jundishapur University of Medical Sciences
City
Ahvaz
Province
Khouzestan
Postal code
6135815751
Approval date
2022-08-17, 1401/05/26
Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1401.074

Health conditions studied

1

Description of health condition studied
Systemic lupus erythematosus
ICD-10 code
M32.9
ICD-10 code description
Systemic lupus erythematosus, unspecified

Primary outcomes

1

Description
SLEDAI scoring based on physical examination and laboratory data
Timepoint
before the start of the study and three months after its start
Method of measurement
Based on the Systemic Lupus Erythematosus Disease Activity Index

2

Description
ESR rate
Timepoint
before the start of the study and three months after its start
Method of measurement
It is measured with ESR analyzer by Western green method

3

Description
arthritis
Timepoint
before the start of the study and three months after its start
Method of measurement
Detailed examination by a rheumatologist for the presence of warmth, sensitivity, swelling or effusion

4

Description
skin rash
Timepoint
before the start of the study and three months after its start
Method of measurement

Skin examination by a rheumatologist for the presence of acute, sub-acute and chronic inflammatory skin rash specific to lupus

5

Description
hair loss
Timepoint
before the start of the study and three months after its start
Method of measurement
With the pull test method

6

Description
mucosal ulcer
Timepoint
before the start of the study and three months after its start
Method of measurement
Examination of the nose and mouth to check for the presence of ulcers

7

Description
Fever
Timepoint
before the start of the study and three months after its start
Method of measurement
Mercury thermometer

8

Description
pleurisy
Timepoint
before the start of the study and three months after its start
Method of measurement
Lung auscultation and lung CT scan if necessary

9

Description
pericarditis
Timepoint
before the start of the study and three months after its start
Method of measurement
Auscultation of the heart ; ECG or echocardiography

10

Description
Complements: C3,C4,CH50
Timepoint
before the start of the study and three months after its start
Method of measurement
by the ELIZA method

11

Description
Anti- ds DNA
Timepoint
before the start of the study and three months after its start
Method of measurement
by ELIZA method, IF

12

Description
platelet
Timepoint
before the start of the study and three months after its start
Method of measurement
Cell counter machine

13

Description
White blood cell
Timepoint
before the start of the study and three months after its start
Method of measurement
Cell counter machine

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: a group of 32 patients with systemic lupus erythematosus, in addition to the routine treatments of this disease (such as:prednisolone ,hydroxychloroquine,methotrexate) take metformin tablets 500 mg daily every 8 hours after meals for three months, the manufacturer of which is Obedi.
Category
Treatment - Drugs

2

Description
Control group:Control group: 32 patients with systemic lupus erythematosus who receive routine treatments of this disease (such as:prednisolone ,hydroxychloroquine,methotrexate) but do not take metformin tablets.
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Golestan hospital

Full name of responsible person
Doctor Noushin Movafagh/ Dr Elham Rajaei

Street address
Golestan blvd, Golestan hospital

City
Ahvaz

Province
Khouzestan

Postal code
6135733118

Phone
+98 61 3320 4500

Email
Golestanjpspital@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Doctor Mehrnoosh Zakerkish

Street address
Golestan Blvd., Ahvaz Jundishapur University of Medical Sciences, Research and Technology Deputy

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3337 3838

Email
research@ajums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz University of Medical Sciences

Proportion provided by this source
30

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
Ahvaz University of Medical Sciences

Full name of responsible person
Noushin Movafagh

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Golestan Blvd, Golestan Hospital, Jundishapur University of Medical Sciences, internal department

City
Ahvaz

Province
Khouzestan

Postal code
6135733118

Phone
+98 61 3320 4504

Email
movafagh-n@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Noushin Movafagh

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Golestan Blvd, Golestan Hospital,internal department

City
Ahvaz

Province
Khouzestan

Postal code
6135733118

Phone
+98 61 3320 4504

Email
movafagh-n@ajums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Noushin Movafagh

Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Golestan blvd,Golestan Hospital,Internal department
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone
+98 61 3320 4504
Email
movafagh-n@ajums.ac.ir

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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data and documents can be shared. Age and clinical symptoms of laboratory findings of eligible patients can be shared
When the data will become available and for how long
The access period starts 6 months after the announcement of the results
To whom data/document is available
Academic institutions
Under which criteria data/document could be used
To improve the quality of treatment of patients with Systemic Lupus erythematosus , it can be sent to university professors and doctors
From where data/document is obtainable
Doctor Noushin Movafagh movafagh-n@ajums.ac.ir
Doctor Sepideh sehhat sehhat.s@ajums.ac.ir
What processes are involved for a request to access data/document
First, the documents or data files are requested from the mentioned researchers through the mentioned emails, then 60 days after the request, the documents will reach the requester
Comments