

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Double-blind placebo-controlled clinical trial of effect of Silybum marianum extract capsules on systemic lupus erythematosus patients

Protocol summary

Study aim

The aim of this study is to evaluate effects of Silybum marianum fruit extract on quality of life and well-being of systemic lupus erythematosus patients

Design

This study is a double-blind and controlled trial, 35 patients with active lupus are assigned in each group. For randomization, the permuted block randomization will be used with quadruple blocks, In order to apply the concealment in the randomization process, unique codes, which is generated by the software, will be used on the drug boxes.

Settings and conduct

All patients referred to Golestan Hospital of Ahvaz, Iran, were assigned randomly in one of the treatment regimens for 4 weeks.

Participants/Inclusion and exclusion criteria

age between 18 to 50, active lupus erythematosus

Intervention groups

control group Oral capsules filled with sugar and starch 3 times per day for 1 month, intervention group: methotrexate, prednisolone and azathioprine (as main treatment) and 140 mg silybum marianum extract 3 times a day for 1 month

Main outcome variables

SLA questionnaire, lupus QOL questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111105008013N9**

Registration date: **2020-07-12, 1399/04/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-12, 1399/04/22**

Update count: **0**

Registration date

2020-07-12, 1399/04/22

Registrant information

Name

Amir Siahpoosh

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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siahpoosh-a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-12, 1399/04/22

Expected recruitment end date

2020-08-12, 1399/05/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double-blind placebo-controlled clinical trial of effect of Silybum marianum extract capsules on systemic lupus erythematosus patients

Public title

clinical trial of effect of Silybum marianum extract capsules on systemic lupus erythematosus patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age 18-50 having active lupus

Exclusion criteria:

diabetes cardiovascular diseases using irrelevant drugs with lupus pregnancy lactation

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the permuted block randomization will be used with quadruple blocks. blocks will be produced by using the online site (www.sealedenvelope.com)

Blinding (investigator's opinion)

Double blinded

Blinding description

Unique codes, which is generated by the software, will be used on the drug boxes. By entering each individual into the study based on the produced sequence, the drug box in which the code is registered, will be assigned to the individual. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Esfand St., Farvardin Blvd., Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6135733184

Approval date

2020-02-01, 1398/11/12

Ethics committee reference number

IR.AJUMS.REC.1398.829

Health conditions studied

1

Description of health condition studied

Systemic Lupus Erythematosus

ICD-10 code

M32

ICD-10 code description

Systemic lupus erythematosus (SLE)

Primary outcomes

1

Description

Score of Quality of life questionnaire

Timepoint

At the intervention beginning and one month later

Method of measurement

Lupus QOL questionnaire

2

Description

Score of Systemic Lupus Erythematosus Activity questionnaire

Timepoint

At the intervention beginning and one month later

Method of measurement

SLA questionnaire

Secondary outcomes

1

Description

Side effects

Timepoint

One month after the intervention beginning

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: Tab Prednisolone 5 mg/day, tab Methotrexate 2.5 mg/day and tabAzathioprine 50 mg/day (main treatment) with 140 mg Milk thistle capsules 3 times a day for one month

Category

Treatment - Drugs

2

Description

Control group: Oral Capsules that filled with sugar and starch 3 times per day for one month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital in Ahvaz

Full name of responsible person

Amir Siahpoosh

Street address

Medicinal Plants Research Center and Department of Pharmacognosy, Faculty of Pharmacy, Ahvaz Jundishapur University of medical Sciences, Ahvaz, Iran

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Amirsiahpoosh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mohamad Badavi

Street address

Jundishapur University of Medical Science, Golestan, Ahvaz

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Amir Siahpoosh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data**Contact****Name of organization / entity**

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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

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

Only a part of data will be shared

When the data will become available and for how long

The access period will be 6 months after the publication of the results

To whom data/document is available

The information obtained will only be available to researchers working in universities and science centers

Under which criteria data/document could be used

Six months after the publication of this study papers, the obtained data will be available to the applicant researchers for further analysis

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail

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

Applicants will be able to access the obtained data from current study by sending an email to the corresponding author up to one month

Comments