Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Double-blinde 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: methotraxate, 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
+98 61 3334 2197

Email address
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-blinde 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 begining and one month later

Method of measurement

Lupus QOL questionnaire

2

Description

Score of Systemic Lupus Erythematosus Activity questionnaire

Timepoint

At the intervention begining 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 Deparment of Pharmacognosy, Faculty of Pharmacy, Ahvaz Jundishapur University of medical Sciences, Ahvaz, Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone
+98 61 3374 3001
Email
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
City
Ahvaz
Province
Khouzestan
Postal code
6135733184
Phone
+98 61 3336 2414
Email
Amirsiahpoosh@yahoo.com
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
Assaciate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Pharmacognosy grouo, Pharmacy Faculty, Jundishapur University of Medical Science, Golestan, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6155883964
Phone
+98 61 3334 2197
Email
Amirsiahpoosh@yahoo.com

Person responsible for scientific 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
Street address
جاده گلستان
City
Ahvaz
Province
Khouzestan
Postal code
6135733184

Phone
+98 61 3334 2197
Email
Amirsiahpoosh@yahoo.com

Person responsible for updating data

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
Street address
Golestan road
City
Ahvaz
Province
Khouzestan
Postal code
6135733184
Phone
+98 61 3334 2197
Email
Amirsiahpoosh@yahoo.com

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