Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the efficacy of atorvastatin with placebo on disease activity in patients with systemic lupus erythematosus

Protocol summary

Summary

This study is a triple-blind, placebo-controlled randomized clinical trial. The aim of study is investigation of the effect of atorvastatin on systemic lupus erythematosus (SLE) activity. The lupus patients in Alzahra hospital divide into two intervention and control groups (45 patients in each of them). After taking consent, total cholesterol, triglyceride, HDL, LDL, urinanalysis, 24-hour urine protein, creatinine, ALT, ESR, CRP, anti-ds DNA, C3, C4, CH50 and CBC will be checked. The Atorvastatin (20 mg/day) and placebo will be prescribed for intervention and control groups, respectively for three months as well as the standard lupus treatment. The above tests will be checked again after three months. SLE activity will be measured and compared by SLEDAI-2K score before the intervention and after three months. Cases with history of allergy to atorvastatin, cyclophosphamide use in last three months, current use of prednisolone > 0.5 mg.kg/day and current use of cyclosporine will not include in this study. Exclusion criteria: Patients who need to receive cyclophosphamide or prednisolone (≥0.5mg/kg/day) due to the severity of their symptoms or signs or complain from unexplained myalgia during the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012081110557N1**
Registration date: **2012-10-02, 1391/07/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-10-02, 1391/07/11

Registrant information

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Alimohammad Fatemi

Name of organization / entity
Isfahan University of Medical Sciences and Health Services

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellery of Research, School of Medicine, Isfahan University of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2012-08-21, 1391/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the efficacy of atorvastatin with placebo on disease activity in patients with systemic lupus erythematosus

Public title

The efficacy of atorvastatin in treatment of Lupus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1- Diagnosis of systemic lupus Erythematosus according to American college of

rheumatology criteria, 2- No allergy to atorvastatin, 3- No cyclophosphamide use in last three months, 4- No current use of prednisolone (≥0.5mg/kg/day) or equivalent dose from other corticosteroids, 5- No current use of cyclosporine, 6- Serum creatinine < 2mg/dl, 7- ALT< 2 x normal, 8- Negative pregnancy test for female patients, 9- No history of hepatitis 10- No history of myositis Exclusion Criteria: 1- Missing of the patients (do not come back for follow up, discontinue the medication), 2- Irregular drug intake, 3- Intolerance to atorvastatin, 4- Need to cyclophosphamide during the study, 5- Need to prednisolone (≥0.5mg/kg/day) or equivalent dose from other corticosteroids during the study, 6- Need to Cysclosporine during the study, 7- Rising of ALT > 2x normal, 8- Unexplained myalgia during the study

Age
From **16 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In this study- from the SLE patients who fulfill the American college of Rhueumatology criteria for SLE and visited in rheumatology clinic (Alzahra Hospital, Isfahan University of Medical Sciences)- ninety patients will be recruit by convenience sampling. After that, they will be divided into intervention and control groups by using random number table. The atorvastatin and placebo will be taken from Sobhan Darou Co. and have similar package which label by A or B. The physicians who give them to the patients do not know which of them is atorvastatin or placebo, as well as who analyze the data.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezarjarib St

City
Isfahan

Postal code
73461-8174

Approval date
2011-11-09, 1390/08/18

Ethics committee reference number
390369

Health conditions studied

1

Description of health condition studied
Systemic Lupus Erythematosus

ICD-10 code
M32

ICD-10 code description
Systemic Lupus Erythematosus

Primary outcomes

1

Description
SLEDAI-2K

Timepoint
Before and three months after intervention

Method of measurement
SLEDAI-2K checklist

Secondary outcomes

1

Description
anti-ds DNA

Timepoint
before and three months after intervention

Method of measurement
ELISA method

2

Description
C3

Timepoint
before and three months after intervention

Method of measurement
ELISA method

3

Description
C4

Timepoint
before and three months after intervention

Method of measurement
ELISA method

4

Description
CH50
Timepoint
before and three months after intervention
Method of measurement
Measurement of hemolytic activity of complement

5

Description
Serum Creatinine
Timepoint
before and three months after intervention
Method of measurement
autoanalyzer

6

Description
Alanine amino transferase
Timepoint
before and three months after intervention
Method of measurement
autoanalyzer

7

Description
Urine protein
Timepoint
before and three months after intervention
Method of measurement
Measurement of 24- hour urine protein

8

Description
Erythrocyte Sedimentation Rate
Timepoint
before and three months after intervention
Method of measurement
Westergreen method

9

Description
C reactive protein
Timepoint
before and three months after intervention
Method of measurement
ELISA method

10

Description
CBS
Timepoint
before and three months after intervention
Method of measurement
blood counting machine

11

Description
Triglyceride
Timepoint
before and three months after intervention
Method of measurement
Calorimetry

12

Description
Total Cholesterol
Timepoint
before and three months after intervention
Method of measurement
Calorimetry

13

Description
HDL
Timepoint
before and three months after intervention
Method of measurement
Calorimetry

14

Description
LDL
Timepoint
before and three months after intervention
Method of measurement
Calorimetry

Intervention groups

1

Description
Atorvastatin (20 mg/day) for 3 months
Category
Treatment - Drugs

2

Description
Placebo (20mg/day) for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Dr.Alimohammad Fatemi
Street address
Sofe St

City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Research, School of Medicine
Full name of responsible person
Dr.Taleb Azarm
Street address
Vice Chancellor For Research, Medical School, Isfahan University Of Medical Science, Hezarjarib St
City
Isfahan
Grant name
Grant code / Reference number
390369
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research, School of Medicine
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences and Health Services
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Person responsible for updating data

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Email
a_fatemi@med.mui.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty