# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Jul 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**

**Name**
Alimohammad Fatemi
**Name of organization / entity**
Isfahan University of Medical Sciences and Health Services
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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
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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**
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## Person responsible for updating data

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## 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*