

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The Anti-inflammatory Effect of Atorvastatin on Rheumatoid Arthritis

#### Protocol summary

##### Summary

This clinical trial will be performed on 30 RA patients, who referred to Imam Reza and Qaem Medical Centers of Mashhad, Iran. Patients will be divided into two groups regard to random block method. The inclusion criteria are as follows: 1) meeting the 2010 ACR/EULAR criteria; 2)  $\geq 18$  years of age; and 3) DAS-28-ESR  $< 3.2$ . The exclusion criteria are: 1) known liver disease; 2) elevated transaminases two months before the study; 3) previous history of myopathy; 4) pregnancy; 5) breastfeeding; 6) use of lipid-lowering agents; and 7) being eligible for taking lipid-lowering agents according to the National Cholesterol Education Program (NCEP). Patients will be divided into two groups: 1) the intervention group receiving 40 mg of atorvastatin, and 2) the control group. Response to treatment and the clinical status of patients will be evaluated using Disease Activity Score (DAS-28) and Visual Analogue Scale (VAS) at weeks zero, four, eight, and twelve, based on the 2010 ACR/EULAR Criteria by two rheumatologists who are blinded to the intervention. Disease activity and laboratory parameters including erythrocyte sedimentation rate (ESR), high-sensitivity C-reactive protein (hs-CRP), DAS-ESR, DAS- hs-CRP, high-density lipoprotein (HDL), low-density lipoprotein (LDL) and liver function test (LFT) will be measured in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016010425816N1**  
Registration date: **2016-03-24, 1395/01/05**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-03-24, 1395/01/05

#### Registrant information

##### Name

Zhaleh Shariat

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 915 113 0199

##### Email address

soltanifara1@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Mashhad University of Medical Sciences

#### Expected recruitment start date

2014-12-31, 1393/10/10

#### Expected recruitment end date

2015-11-30, 1394/09/09

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Anti-inflammatory Effect of Atorvastatin on Rheumatoid Arthritis

#### Public title

Evaluation of the Anti-inflammatory Effect of Atorvastatin on Patients with Rheumatoid Arthritis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

The inclusion criteria are as follows: 1) meeting the 2010 ACR/EULAR criteria; 2)  $\geq 18$  years of age; and 3) DAS-28-ESR  $< 3.2$ . The exclusion criteria are : 1) known liver disease; 2) elevated transaminases two months before the study; 3) previous history of myopathy; 4)

pregnancy; 5) breastfeeding; 6) use of lipid-lowering agents; and 7) being eligible for taking lipid-lowering agents according to the National Cholesterol Education Program (NCEP).

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **30**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

Two rheumatologists are blinded to the intervention; evaluate the patients every 4 weeks.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

##### **Street address**

Mashhad University of Medical Sciences

##### **City**

Mashhad

##### **Postal code**

##### **Approval date**

2010-09-23, 1389/07/01

##### **Ethics committee reference number**

IR.mums.REC.1389.71

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Rheumatoid Arthritis

#### **ICD-10 code**

M05

#### **ICD-10 code description**

XIII Diseases of the musculoskeletal system and connective tissue

## **Primary outcomes**

### **1**

#### **Description**

Disease Activity Index

#### **Timepoint**

Before intervention, after 4 weeks, 8 weeks and 12 weeks

#### **Method of measurement**

Clinical

### **2**

#### **Description**

Lipid profile

#### **Timepoint**

Before intervention, after 4 weeks, 8 weeks and 12 weeks

#### **Method of measurement**

Laboratory

## **Secondary outcomes**

### **1**

#### **Description**

ESR

#### **Timepoint**

Before intervention, after 4 weeks, 8 weeks and 12 weeks

#### **Method of measurement**

Laboratory

### **2**

#### **Description**

hs-CRP

#### **Timepoint**

Before intervention, after 4 weeks, 8 weeks and 12 weeks

#### **Method of measurement**

Laboratory

### **3**

#### **Description**

Liver function test

#### **Timepoint**

Before intervention, after 4 weeks, 8 weeks and 12 weeks

#### **Method of measurement**

Laboratory

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Atorvastatin (40 mg daily)

#### **Category**

Treatment - Drugs

## 2

### Description

control group: placebo

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza Hospital and Qaem Hospital

##### Full name of responsible person

Zhaleh Shariati

##### Street address

Rheumatology department, Emam Reza hospital,  
Emam Reza Square, Ebne Sina Avenue, Mashhad, Iran

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Mashhad University of  
Medical Sciences

##### Full name of responsible person

Zhaleh Shariati

##### Street address

Rheumatology department, Emam Reza hospital,  
Emam Reza Square, Ebne Sina Avenue, Mashhad, Iran

##### City

Mashhad

##### Grant name

-

##### Grant code / Reference number

-

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

Yes

##### Title of funding source

Vice Chancellor for research of Mashhad University of  
Medical Sciences

##### 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

Mashhad University of Medical Sciences

### Full name of responsible person

Zhaleh Shariati

### Position

Rheumatologist

### Other areas of specialty/work

### Street address

Rheumatology department, Emam Reza hospital,  
Emam Reza Square, Ebne Sina Avenue, Mashhad, Iran

### City

Mashhad

### Postal code

### Phone

+98 51 3623 1061

### Fax

+98 913 791 3316

### Email

sh79316@yahoo.com

### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Zhaleh Shariati

#### Position

Rheumatologist

#### Other areas of specialty/work

#### Street address

Rheumatology department, Emam Reza hospital,  
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## Person responsible for updating data

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Zhaleh Shariati

#### Position

Rheumatologist

#### Other areas of specialty/work

#### Street address

Rheumatology department, Emam Reza hospital,  
Emam Reza Square, Ebne Sina Avenue, Mashhad, Iran

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**Phone**

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**Fax**

**Email**

**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*