Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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) ≥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)
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+98 915 113 0199
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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) ≥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
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Person responsible for updating data

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Postal code

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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