

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

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) ≥ 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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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Rheumatologist

Other areas of specialty/work

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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