

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of statin effect on the disease activity in rheumatoid arthritis

Protocol summary

Summary

The goal of this study is evaluation of oral Atorvastatin and Simvastatin effect on rheumatoid arthritis disease activity ((DAS28 score). Population study will be rheumatoid arthritis patients referred to the Rheumatology Clinic of Alzahra Hospital. Sample size in this study is 150. This study is a randomized double blind controlled trial that will start at the spring 2010 and will continue to spring 2011. The primary endpoint is improvement of clinical symptoms and laboratory parameters of patients following oral consumption of Simvastatin or Atorvastatin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811161778N2**

Registration date: **2010-04-06, 1389/01/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-04-06, 1389/01/17

Registrant information

Name

Mansour Salesi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1265 1983

Email address

salesi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellery for research

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of statin effect on the disease activity in rheumatoid arthritis

Public title

Statins and rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Rheumatoid arthritis patients (proved by ACR criteria) and 3 months passed from their diagnosis. Exclusion criteria: Drug reaction, lapse from the study, Immigration or death, contraindications for statins (pregnancy, lactation, abnormal liver function tests abnormality

Age

From **16 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

Street address

Hezar Jarib Boulevard

City

Isfahan

Postal code

8158697851

Approval date

2008-11-22, 1387/09/02

Ethics committee reference number

188099

Health conditions studied**1****Description of health condition studied**

Rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Seropositive rheumatoid arthritis

Primary outcomes**1****Description**

Clinical and laboratory findings

Timepoint

Before the study and 3 months later

Method of measurement

DAS28, ESR, VAS

Secondary outcomes**1****Description**

Better control of rheumatoid arthritis and prevention of joint destruction

Timepoint

Before the study and 3 months later

Method of measurement

DAS28, ESR, VAS

Intervention groups**1****Description**

One placebo tablet per day for 3 months

Category

Placebo

2**Description**

Atorvastatin oral pills 40 mg one tablet per day for 3 months

Category

Treatment - Drugs

3**Description**

Simvastatin oral pills 40 mg one tablet per day for 3 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Mansour Salesi

Street address

Sofe Avenue

City

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellery of research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Fallah

Street address

No#4 building, vice chancellery of research, Isfahan University of Medical Sciences

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes
Title of funding source
Vice chancellor of research, Isfahan 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
Isfahan University of Medical Sciences
Full name of responsible person
Mansour Salesi
Position
Rheumatologist/Assistant professor
Other areas of specialty/work
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Person responsible for scientific inquiries

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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