

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### A clinical trial on the efficacy of Raloxifene on disease activity and glucocorticoid-induced osteoporosis in postmenopausal women with Rheumatoid Arthritis

#### Protocol summary

##### Summary

We select 40 postmenopausal women suffering from rheumatoid arthritis in order to study efficacy of Raloxifene in disease activity of rheumatoid arthritis in post menopause and randomly divide them into intervention group and placebo group. Patients who fulfill at least 4 criteria of ACR-1987 criteria for rheumatoid arthritis and have DAS28-ESR in range of 2.5-5.5 are included in study, and Patients with thromboembolic events or other rheumatologic disorders are excluded. Evista tab 60mg/day and placebo are administered double blind. In the beginning, bone mineral density (BMD) assessment is carried out from all patients and then Alendronate is discontinued in 2 groups. In first 3 months, in addition to Evista and placebo, MTX tab 2.5mg is given to patients and they are allowed to consume NSAID with accurate record of its dosage. Patients visit rheumatologist monthly in these 3 months. At the end of month 3, disease activity and probable complications as the main outcome measures are evaluated and compared in 2 groups. Classic regimen should be started for every patient who doesn't enter remission phase in first 3 months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015052022334N1**  
Registration date: **2016-12-27, 1395/10/07**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-12-27, 1395/10/07

#### Registrant information

##### Name

Sara Saeidi Shahri

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3879 5031

##### Email address

saeidis891@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Research Chancellor of Mashhad University of Medical Sciences

#### Expected recruitment start date

2017-01-20, 1395/11/01

#### Expected recruitment end date

2017-02-19, 1395/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A clinical trial on the efficacy of Raloxifene on disease activity and glucocorticoid-induced osteoporosis in postmenopausal women with Rheumatoid Arthritis

#### Public title

clinical trial on the efficacy of Raloxifene on disease activity in Rheumatoid Arthritis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Patients should be selected from postmenopausal women; Patients should fulfill at least 4 criteria of ACR-1987 for Rheumatoid Arthritis; Patients should have DAS28-ESR in range of 2.5-5.5. Exclusion criteria: Patients with thromboembolic events; Patients with other rheumatologic disorders; Patients with severe postmenopausal symptoms; Patients with known psychological disorders

#### Age

From **50 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

### 1

#### Registry name

clinicaltrial.gov

#### Secondary trial Id

NCT02982083

#### Registration date

2016-12-02, 1395/09/12

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Administration Center(Qoreishi Building), Daneshgah St.

##### City

Mashhad

##### Postal code

13944-91388

#### Approval date

2016-02-02, 1394/11/13

#### Ethics committee reference number

471905

## Health conditions studied

### 1

#### Description of health condition studied

Rheumatoid Arthritis

#### ICD-10 code

M06.9

#### ICD-10 code description

Rheumatoid arthritis, unspecified

## Primary outcomes

### 1

#### Description

Disease activity of rheumatoid arthritis

#### Timepoint

monthly in first 3 month, every 2 months since 5th month

#### Method of measurement

based on DAS28-ESR formula

### 2

#### Description

Complications of Raloxifene

#### Timepoint

monthly in first 3 month, every 2 months since 5th month

#### Method of measurement

questionare

## Secondary outcomes

### 1

#### Description

Bone mineral density

#### Timepoint

in the begining and end of the study

#### Method of measurement

Total BMD test

## Intervention groups

### 1

#### Description

150mg capsule containing Evista tablet, 60 mg oral, daily til 12 months

#### Category

Treatment - Drugs

### 2

#### Description

Placebo capsule, 150 mg, oral, daily til 12 months

#### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Rheumatic diseases research center of Mashhad  
University of Medical Sciences

**Full name of responsible person**

**Street address**

**City**

Mashhad

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Research Chancellor of Mashhad University of Medical  
Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

University St., Ghorashy Building, Research  
Chancellor of Mashhad University of Medical Sciences

**City**

Mashhad

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Research Chancellor 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**

Sara Saeidi Shahri

**Position**

Medical student

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Maryam Sahebari

**Position**

Associate professor

**Other areas of specialty/work**

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Koohsangi st.

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## Person responsible for updating data

### Contact

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Sara Saeidi Shahri

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Medical student

**Other areas of specialty/work**

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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*