

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of pioglitason on disease activity and inflammatory markers of rheumatoid arthritis

Protocol summary

Summary

Objectives: The effect of pioglitason on disease activity and inflammatory markers of rheumatoid arthritis.

Design: This study is a double-blind with random sampling method. **Setting and conduct:** A total of 100 patients will be chosen with rheumatoid arthritis, that has not responded to Disease-modifying anti rheumatic dmgs (DMARD) and then DAS-28 > 3.2 is considered as active disease. Patients with DAS-28 > 3.2 are to be included in the study. Patients will be examined under a physical examination and review of the swollen and painful joints number and activity level of disease measured by visual Analogue Scale. Then before the study experiments of ESR-hsCRP-Cholestrol-HDL-TG-BUN-Cr-AST-ALT-ALK-P is done. After that patients randomly will be divided into two equal groups, in the first group, they will be treated with pioglitazone 30 mg pills daily for 12 weeks. In the second group, they will be treated with placebo and considered as control. In fourth and eighth week, the patients again will be examined for medication compliance and possible side effects if during the study patients were drug-induced complications, they will be excluded from the study and new ones will be replaced. At the end of the twelfth week, again will be obtained DAS28 score, Analogue scale and other test, and the results will be analyzed. **Inclusion criteria:** (a) aged 20-65 years (b) patients with rheumatoid arthritis (ACR) criteria (c) disease activity based on DAS-28 > 3.2 (d) informed consent. **Exclusion criteria:** (a) comorbidities such as diabetes mellitus, kidney and liver diseases, etc. (b) severe obesity (BMI > 35) (c) uncontrolled hypertension (d) congestive heart failure (CHF) (e) side effects of pioglitazone drug (f) acute and active infectious disease (g) Hyperlipidemia TG > 200, total cholestal > 220 (h) indicated to biological drugs

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111425031N1**

Registration date: **2016-01-24, 1394/11/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-24, 1394/11/04

Registrant information

Name

Fatemeh Rafiei

Name of organization / entity

Arak University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 86 3226 5732

Email address

a.rafiee@tafreshu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-07-02, 1393/04/11

Expected recruitment end date

2014-12-24, 1393/10/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pioglitason on disease activity and inflammatory markers of rheumatoid arthritis

Public title

The effect of pioglitason on rheumatoid arthritis disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 20-65 years old; patients with rheumatoid arthritis (ACR) criteria; disease activity based on DAS-28 > 3.2; signed informed consent.

Exclusion criteria: comorbidities such as diabetes mellitus, kidney and liver diseases, etc; severe obesity (BMI > 35); uncontrolled hypertension; congestive heart failure (CHF); side effects of pioglitazone drug; acute and active infectious disease; hyperlipidemia TG > 200, total cholesterol > 220; indicated to biological drugs.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Ethics Committe of Arak University of Medical Sciences

Street address

Basij Square, Sardasht, Arak, Iran

City

Arak

Postal code

Approval date

2014-05-05, 1393/02/15

Ethics committee reference number

93-162-4

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

Disease Activity Score (DAS-28)

Timepoint

before and twelve weeks after intervention

Method of measurement

by means of DAS-28 validated questionnaire

2

Description

The number of painful and swollen joints

Timepoint

before and twelve weeks after intervention

Method of measurement

visual scale

3

Description

Tests (ESR-hs CRP-Cholesterol-HDL-TG-BUN-Cr-AST-ALT-ALK-P)

Timepoint

before and twelve weeks after intervention

Method of measurement

Laboratory Kit

Secondary outcomes

empty

Intervention groups

1

Description

For twelve weeks, patients treated with Pioglitazone pills, daily 30 mg in intervention group

Category

Treatment - Drugs

2

Description

For twelve weeks use Pioglitazone pills that filled with starch as placebo in control group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-Almomenin Hospital

Full name of responsible person

Dr. Talaat Shahmoradi

Street address

Basij Square, Sardasht, Arak, Iran

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Arak University of Medical Sciences

Full name of responsible person

Dr. Sepideh Mortagi

Street address

Amir-al-Momenin Hospital, Basij Square, Sardasht, Arak, Iran

City

Arak

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 Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr. Talaat Shahmoradi

Position

MD, Resident of Internal Medicine

Other areas of specialty/work**Street address**

Nastaran Alley, Navid Street, Mostafa-Khomeini Settlements, Arak, Markazi, Iran

City

Arak

Postal code

3818134556

Phone

+98 86 3366 0666

Fax**Email**

t.shamoradi@arakmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Talaat Shamoradi

Position

MD, Resident of Internal Medicine

Other areas of specialty/work**Street address**

Nastaran Alley, Navid Street, Mostafa-Khomeini Settlements, Arak, Markazi, Iran

City

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3818134556

Phone

+98 86 3366 0666

Fax**Email**

t.shamoradi@arakmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Science

Full name of responsible person

Dr. Talaat Shahmoradi

Position

MD, Resident of Internal Medicine

Other areas of specialty/work**Street address**

Nastaran Alley, Navid Street, Mostafa-Khomeini Settlements, Arak, Markazi, Iran

City

Arak

Postal code

3819797457

Phone

+98 86 3366 0666

Fax**Email**

t.shamoradi@arakmu.ac.ir

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