Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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.rafiei@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 cholestal> 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
Arak
Postal code
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