

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of metformin on decreasing activity and severity of rheumatoid arthritis disease (pilot study)

Protocol summary

Study aim

Determination of the effect of metformin on decreasing the activity and severity of rheumatoid arthritis disease

Design

This is a controlled double-blind clinical trial study conducted on 60 patients with rheumatoid arthritis. Patients (N= 30 per group) are randomly treated with metformin or placebo for 12 weeks.

Settings and conduct

60 patients referred to the rheumatology clinic of Golestan and Imam Khomeini hospitals in Ahvaz. They are classified based on mild to high severity of rheumatoid arthritis according to ACR2010 criteria who are randomly divided into two groups of 30 people. The intervention group receives metformin 500 mg twice a day and the case group also receives placebo 500 mg twice a day. After 12 weeks, activity and severity of disease based on DAS28 score as well as TJC, CRP, and ESR of patients are evaluated by a rheumatologist in two groups.

Participants/Inclusion and exclusion criteria

Patients with moderate to high severity of rheumatoid arthritis based on DAS28 scale

Intervention groups

Duration of illness over 3 years, there is significant kidney disorder that forbids from using metformin (GFR <30), pregnancy, significant heart failure (EF <50%), chronic hepatic impairment or acute liver failure, having diabetes or previous and recent use of metformin, the last 3 months of anti-inflammatory drugs, new drug added to control patient symptoms during treatment

Main outcome variables

Disease severity; erythrocyte sedimentation rate (ESR); swollen joint count (SJC); tender joint count (TJC); CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190916044787N1**

Registration date: **2019-10-01, 1398/07/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-01, 1398/07/09**

Update count: **0**

Registration date

2019-10-01, 1398/07/09

Registrant information

Name

Sajedeh Igder

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3292 1839

Email address

igder.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of metformin on decreasing activity and severity of rheumatoid arthritis disease (pilot study)

Public title

The effect of metformin on decreasing the severity of rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with moderate to high severity of rheumatoid arthritis based on the DAS28 scale

Exclusion criteria:

Duration of illness over 3 years There is significant kidney disorder that forbids from using metformin (GFR <30) Pregnancy Significant heart failure (EF <50%) Chronic hepatic impairment or acute liver failure Having diabetes or previous and recent use of metformin The last 3 months of anti-inflammatory drugs New drug added to control patient symptoms during treatment

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

By random block permutation, individuals will be divided into two groups. The block sizes can be 4, 6 and so on. 6 blocks including 4 characters will be considered; AABB, ABAB, BBAA, BABA, ABBA, and BAAB. We will sample from the six blocks with replacement to the extent that the sample size is completed. In this case, a sequence of letters will be obtained, in which individuals will be randomly divided into two equal groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

All medications will be in similar and dark packets. A numeric label will be on each pack of medications. Patient and researcher will not inform of the number assigned to the relevant group. Then, according to the random sequence based on random block permutation, the packets of medications will be given to the researcher.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences, Golestan Blvd., Golestan Town

City

Ahvaz

Province

Khuzestan

Postal code

61357-157941

Approval date

2018-09-22, 1397/06/31

Ethics committee reference number

IR.AJUMS.REC.1397.429

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 severity

Timepoint

At baseline and after treatment (12 weeks)

Method of measurement

DAS28

2

Description

Erythrocyte sedimentation rate (ESR)

Timepoint

At baseline and after treatment (12 weeks)

Method of measurement

Western Green analysis

3

Description

Swollen joint count (SJC)

Timepoint

At baseline and after treatment (12 weeks)

Method of measurement

Examination and clinical judgment of the physician

4

Description

Tender joint count (TJC)

Timepoint

At baseline and after treatment (12 weeks)

Method of measurement

Examination and clinical judgment of the physician

5

Description

CRP

Timepoint

At baseline and after treatment (12 weeks)

Method of measurement

Aagglutination test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Metformin (Najo Company, Iran) is given at a dose of 500 mg twice a day for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo (made in School of Pharmacy, Ahvaz University of Medical Sciences) is given at a dose of 500 mg twice a day for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Sajedeh Igder

Street address

Imam Khomeini Hospital.,Azadegan Ave

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2

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

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Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Jundishapur University of Medical Sciences,

Chancellor for Research and Technology

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Sajedeh Igder

Position

Internal Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate Professor

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Subspecialist

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available