

# 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)

##### Phone

+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

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6193673166

**Phone**

+98 61 3222 2114

**Email**

himam@ajums.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

Golestan Hospital

**Full name of responsible person**

Sajedeh Igder

**Street address**

Golestan Hospital, Farvardin Ave., Golestan

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135733118

**Phone**

+98 61 3374 3001

**Email**

Drsajedehigder3393@gmail.com

**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  
Development, Golestan Blvd., Golestan Town

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

61357-15794

**Phone**

+98 61 3373 8286

**Fax**

**Email**

info@ajums.ac.ir

**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

**Street address**

Imam Khomeini Hospital., Azadegan Ave

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6193673166

**Phone**

+98 61 3222 2114

**Email**

Drsajedehigder3393@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Karim Mowla

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Jundishapur University of Medical Sciences, Golestan Bldv.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733118

**Phone**

+98 61 3374 3001

**Email**

Mowla\_k@yahoo.com

## Person responsible for updating data

### 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

**Street address**

Imam Khomeini Hospital., Azadegan Ave.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6193673166

**Phone**

+98 61 3222 2114

**Email**

Drsajedehigder3393@gmail.com

## 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