

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Evaluation of interaction of mTOR signaling pathway and improvement of symptoms in osteoarthritis patients treated with metformin

#### Protocol summary

##### Study aim

Objectives Goals: Determine the frequency of allele and genotype of rs2279115 (BCL2) and rs2277680 (CXCL16) polymorphism by PCR-RFLP method, measurement of serum CXCL16 protein using by ELISA kit and measurement of BCL2 , miR-451 and miR-15b / 16 expression in osteoarthritis patients with Metformin Recipient using Real Time-PCR.

##### Design

The controlled, parallel group, single-blind, randomized trial, on 100 patients. random allocation is used for performing a block randomization with randomly selected block sizes of 4.

##### Settings and conduct

Drug prescription is as follows: The first week, 500 mg daily, the second week, 1000 mg daily and 1500 mg daily until the end of the study for 16 weeks. the clinical status are evaluated by doctor (using a questionnaire WOMAC) and sampling at weeks 0 and 16 study in Rajaei clinic are performed. study is Single-blind in which the placement of individuals in study groups is unknown to the principal researcher.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included BMI>25 and inflammatory osteoarthritis. Exclusion criteria: cancer; autoimmune disease; age under 18; diabetes mellitus and inflammatory bowel disease.

##### Intervention groups

Patients in the treatment group take metformin in addition to nonsteroidal anti-inflammatory (NSAID) drugs, but patients do not take another medicine, except NSAIDs in the control group.

##### Main outcome variables

Reducing pain; weight loss; reducing inflammation of the joints; improving the joint movement

#### General information

##### Reason for update

##### Acronym

mTOR

##### IRCT registration information

IRCT registration number: **IRCT20150202020908N2**

Registration date: **2020-12-24, 1399/10/04**

Registration timing: **retrospective**

Last update: **2020-12-24, 1399/10/04**

Update count: **0**

##### Registration date

2020-12-24, 1399/10/04

##### Registrant information

###### Name

Negar Firouzabadi

###### Name of organization / entity

Shiraz university of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3635 9337

###### Email address

firouzabadi@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-22, 1398/04/01

##### Expected recruitment end date

2019-12-22, 1398/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of interaction of mTOR signaling pathway and

improvement of symptoms in osteoarthritis patients treated with metformin

## Public title

Evaluation of the molecular effects of metformin and improvement of symptoms in osteoarthritis patients

## Purpose

Basic science

## Inclusion/Exclusion criteria

### Inclusion criteria:

Obesity Inflammatory osteoarthritis

### Exclusion criteria:

Autoimmune disease Age under 18 years old Cancer Inflammatory bowel disease Diabetes mellitus

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Investigator

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The lead researcher conducting research experiments on the collected samples is blinded and unaware of whether or not metformin was used by participants.

## Placebo

Not used

## Assignment

Parallel

## Other design features

The study was performed on patients who received medication in one group and did not receive medication in the other.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Immam hossein Square., Karim Khan Zand Blvd.

##### City

Shiraz

##### Province

Fars

##### Postal code

7134845794

## Approval date

2019-10-26, 1398/08/04

## Ethics committee reference number

IR.SUMS.REC.1398.1010

## Health conditions studied

### 1

#### Description of health condition studied

Osteoarthritis

#### ICD-10 code

M17

#### ICD-10 code description

Osteoarthritis of knee

## Primary outcomes

### 1

#### Description

WOMAC questionnaire score

#### Timepoint

At the beginning of the study (before the intervention) and 16 weeks after starting metformin

#### Method of measurement

WOMAC questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Osteoarthritis patients with high-BMI who take metformin in addition to their previous treatment. In the first week, 500 mg daily, the second week 1000 mg daily and then 1500 mg daily until the end of the study for 16 weeks, metformin is given. Clinical evaluation is done by the physician (using the WOMAC questionnaire) and sampling at weeks 0 and 16.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Osteoarthritis patients with high-BMI who do not take metformin and continue their previous treatment.

#### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Bone & Joint Disease Research Center

**Full name of responsible person**

Mohammad Tahami

**Street address**

Chamran hospital, Chamran Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

7194815644

**Phone**

+98 71 3623 4504

**Email**

mohammad.tahami@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Abbas Rezaianzadeh

**Street address**

Seventh floor, Vice Chancellor for Research and Technology, Central building of Shiraz University of Medical Sciences, Zand St.

**City**

Shiraz

**Province**

Fars

**Postal code**

713481433

**Phone**

+98 71 3212 2430

**Email**

vcrdep@sums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohammad Tahami

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

**Street address**

Shahid Chamran Hospital., Chamran Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

7146864685

**Phone**

+98 71 3623 4504

**Fax****Email**

mohammad.tahami@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Negar Firouzabadi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Karafarin Ave., Rokn abad Town., Km 5 Shiraz-Isfahan Highway

**City**

Shiraz

**Province**

Fars

**Postal code**

7146864685

**Phone**

+98 71 3242 4128

**Email**

Firouzabadi@sums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Nahid Alimoradi

**Position**

PhD candidate

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Karafarin Ave., Rokn abad Town., Km 5 Shiraz-Isfahan Highway

**City**

Shiraz

**Province**

Fars

**Postal code**

7146864685

**Phone**

+98 71 3242 4128

**Email**

nahid.alimoradi@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Confidentiality of data

**Study Protocol**

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Clinical and molecular data

**When the data will become available and for how long**

After 24 months

**To whom data/document is available**

Researchers

**Under which criteria data/document could be used**

On request

**From where data/document is obtainable**

Principal researcher

**What processes are involved for a request to access data/document**

Electronic request

**Comments**