

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaianzadeh

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

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Position

PhD candidate

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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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