Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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 scienece
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
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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

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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