Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effectiveness of metformin in WOMAC index of overweight knee osteoarthritis patients

Protocol summary

Study aim
Evaluation of the effectiveness of metformin in WOMAC index of overweight knee osteoarthritis patients

Design
Clinical trial with two intervention groups, with parallel groups, double-blind, randomized block design, phase 2 on 88 patients.

Settings and conduct
The control group give 500mg placebo (drug formulation without metformin)& the intervention group give 500mg metformin tablets once a day for 4 months.The study was double-blind. Examination of serum blood sugar levels, alanine aminotransferase, aspartate aminotransferase and filtration rate glomeruli at the beginning of the study & 4 months later. questionnaire (WOMAC) at the beginning of the study, month 4 . visual pain scale (VAS) monthly. Then the collected information will be classified and analyzed using SPSS software.

Participants/Inclusion and exclusion criteria
Patients who have knee osteoarthritis grades 2 & 3 according to the Kellgren and Lawrence criteria 50 to 75 years . BMI ≥24 kg/m2. Primary Osteoarthritis No history of performing knee arthroscopy and injecting corticosteroids in the knee within less than 6 months from the beginning of the study No history of Type 1 or type 2 diabetes mellitus Exclusion criteria Severe knee trauma/Estimated glomerular filtration rate of less than 60 ml/min/1.73 m2/ Allergic to metformin hydrochloride/injecting corticosteroids in the knee during study

Intervention groups
Group A: group receiving metformin 500 mg daily Group B: group receiving daily placebo pills

Main outcome variables
WOMAC,VAS PAIN SCORE

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200522047538N2**
Registration date: **2024-01-22, 1402/11/02**
Registration timing: **prospective**

Last update: **2024-01-22, 1402/11/02**
Update count: **0**

Registration date
2024-01-22, 1402/11/02

Registrant information

Name
Maryam Kiani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 17 3432 3594

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of metformin in WOMAC index of overweight knee osteoarthritis patients

Public title

Evaluation of the effectiveness of metformin in WOMAC index of overweight knee osteoarthritis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who, based on the radiography and ACR criteria, have knee osteoarthritis grades 2 & 3 according to the Kellgren and Lawrence criteria (Kellgren and Lawrence grade 2, the presence of osteophytes and joint space narrowing & grade 3 confirming the presence of more numbers of sclerosis and osteophyte). 50 to 75 years olds Man or woman BMI body mass index (≥24 kg/m2) VAS Knee pain score≥ 2 on 10 Primary Osteoarthritis (not secondary OA due to trauma or inflammatory arthritis) The person is willing and able to follow the study instructions and go to the clinic for a visit No history of performing knee arthroscopy and injecting corticosteroids in the knee within less than 6 months from the beginning of the study No allergy to any of the compounds used in the study No history of severe trauma in the knee area No history of other rheumatic diseases such as rheumatoid arthritis, psoriatic arthritis and others No active malignancy, cancer or other life-destructive diseases and Type 1 or type 2 diabetes mellitus, hypoxic conditions (corpulmonary-congestive heart failure-acute MI-peripheral artery disease), uncontrolled high blood pressure No Clinical manifestation of liver dysfunction or elevated alanine aminotransferase/aspartate ami- notransferase levels exceeding 2 times the upper limit of normal values GFR glomerular filtration rate higher than ml/min/1.73m2-60 No history of systemic corticosteroids using Not using of alcoholic substances No history of Conditions affecting the absorption of oral drugs (e.g., post gastrectomy and malabsorption syndrome) No history of using metformin in the last 30 days

Exclusion criteria:

Injecting of corticosteroids in the knee within the study Estimated glomerular filtration rate of less than 60 ml/min/1.73 m2; Allergic to metformin hydrochloride; Severe knee trauma during study

Age

From **50 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method will be used to generate a sequence of random numbers. In this method, 40 blocks of size 4 and 25 blocks of size 2 are randomly selected from the combination of letters A and B with a table of random numbers. The list of blocks of size two are 1:AB, 2:BA and the list of blocks of size four are: 1:AABB, 2:ABBA, 3:BBAA, 4:BAAB, 5:BABA, 6:ABAB. To select blocks of size 2, 25 numbers are randomly selected from the table of random numbers, then if this number is from 0 to 4, the first block is selected, and if the number is from 5 to 9, the second block is selected. To select blocks of size 4, 40 numbers between 1 and 6 are randomly selected from the table of random numbers, then if this number is 1, the first block is size 4, and if the selected number is 2, then the second block and so on for other blocks. are selected Allocation Concealment method: The sequence obtained from the randomization method will be recorded on separate sheets, then the obtained sheets will be placed in non-transparent envelopes and the specified treatment will be applied to the patients in the order of arrival of the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients and doctors evaluating the interventions designed in the study or the outcomes after the intervention (rheumatology assistant and rheumatology subspecialist) will not know about the group in which the patient is examined. All interventions in both groups will be designed similarly and the procedure will be the same on all samples in all groups. The drugs used will also be supplied in the same form and packaging so that it is not possible to identify the study group during the study process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

research ethics committee of imam Reza hospital Educational Research and treatment Center-Mashhad U

Street address

Imam Reza (AS) Educational Research and Treatment Center, Ibn Sina Street, Imam Reza (AS) Hospital Square, Razavi Khorasan

City

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Province

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Postal code

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Approval date

2023-09-18, 1402/06/27

Ethics committee reference number

IR.MUMS.IRH.REC.1402.128

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 INDEX of osteoarthritis

Timepoint

evaluation of WOMAC index before the study and 4 month later

Method of measurement

The Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire

Secondary outcomes

1

Description

The Visual Analogue Scale (VAS) pain score

Timepoint

before the start of the intervention and four consecutive month after the start of the intervention

Method of measurement

The Visual Analogue Scale (VAS) pain score 0-10

Intervention groups

1

Description

Intervention group: metformin tablets (ingredients: microcrystalline cellulose, hydroxypropylmethylcellulose, magnesium stearate, and metformin hydrochloride) Kushan Pharmed company - 500 mg per day with food - during 4 months - patient educate about gastrointestinal complications and Improvement of symptoms by continuing to take the drug.

Category

Treatment - Drugs

2

Description

Control group: Placebo pill (ingredients: microcrystalline cellulose, hydroxypropyl methylcellulose, magnesium stearate) formulated by the Mashhad Faculty of Pharmacy, one pill per day with food for 4 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Educational, Research and Treatment Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Mashhad 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
It will be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used

There are no special conditions.

From where data/document is obtainable

Dr. Maryam Kiani Phone number :00989113778569
Email: kiani.m94@gmail.com

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

The applicant should provide his / her study file and the purpose of receiving the data in the form of an email with his / her research file (research plan), then after 3 months the file will be provided to the person

Comments