

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of two types of intra-articular injections including hyaluronic acid and corticosteroids in patients with mild to moderate knee osteoarthritis

Protocol summary

Study aim

Comparison of the effect of intra-knee injections in patients with knee osteoarthritis including injection of corticosteroids and hyaluronic acid over 6 weeks and determining the best injection therapy for patients with mild to moderate osteoarthritis

Design

They will be randomly divided into two groups. Assignment of patients in two groups using the method of table of numbers will be random. The first group is hyaluronic acid injection and the second group is corticosteroid injection. Sample size of 50 patients

Settings and conduct

The first group will be treated with injectable glucocorticoids and the second group with hyaluronic acid (HA). One injection will be given. Patients of all groups will be evaluated at the beginning of treatment and 6 weeks later by the visual pain scale and WOMAC score. The correction will be done using a random number table. Location of specialized clinic of Imam Reza Hospital and doctors' office

Participants/Inclusion and exclusion criteria

Eligible individuals must meet all of the following criteria: Osteoarthritis of the knee, age 70-50 years, Visual Pain Scale (VAS) score greater than 4 at the beginning of treatment, no inflammatory joint disease, patients with a WOMAC score of at least 60/96 and enrollment satisfaction. Exclusion criteria: Rheumatic disease, Chronic diseases such as diabetes and hypertension, Secondary osteoarthritis, Systemic disorders, Inflammatory joint disease, Visual pain scale (VAS) score less than 4 in the joint at the beginning of treatment, Major deviation Axial, coagulopathies, severe cardiovascular disease, active infection, and immune disorders.

Intervention groups

Intervention group: The group in which hyaluronic acid is

injected into the knee. Control group: The group in which corticosteroids are injected into the knee

Main outcome variables

Visual analog scale score, Osteoarthritis index score of Western Universities (WOMAC)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210511051258N1**

Registration date: **2022-02-13, 1400/11/24**

Registration timing: **retrospective**

Last update: **2022-02-13, 1400/11/24**

Update count: **0**

Registration date

2022-02-13, 1400/11/24

Registrant information

Name

Alireza Ghoreishi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-10, 1400/04/19

Expected recruitment end date

2021-08-10, 1400/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two types of intra-articular injections including hyaluronic acid and corticosteroids in patients with mild to moderate knee osteoarthritis

Public title

Comparison of the effect of two types of intra-articular knee injections

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Be between 50 and 70 years old. Have a visual acuity scale (VAS) score greater than 4 in the knee joint at the start of treatment. Absence of inflammatory joint disease Proof of osteoarthritis in patients with a WOMAC score of at least 60 out of 96

Exclusion criteria:

Withdraw from the study Existence of severe cardiovascular diseases Existence of active infection and immune disorders People who are very young People with chronic diseases such as diabetes and hypertension, secondary osteoarthritis, systemic disorders, coagulopathies

AgeFrom **50 years** old to **70 years** old**Gender**

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

Intra-articular injection of both knees

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of patients in two groups will be using the random number table method. In this way, the researcher puts his hand on one of the numbers and starts moving in the right direction and records the numbers and assigns them to different groups. If he reaches an even number on the way, the person goes to the treatment group and if he reaches the number, the patient Will be placed in the control group. Based on the sample size of the research, a number of envelopes with aluminum wrappers are prepared in order to obscure the contents of the envelopes, and each of the random sequences created is recorded on a card, and the cards are placed in the envelopes respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface, and

finally the letter envelopes are glued and placed in a box, respectively, at the beginning of the registration of participants. According to the order of entry of eligible participants in the study, one of the envelopes will be opened in order and the assigned group of the participant will be revealed, the first group will be treated with glucocorticoids and the second group will be treated with hyaluronic acid.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Birjand University of Medical Sciences

Street address

Ghaffari blvd, birjand medical university

City

Birjand

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Postal code

9717853577

Approval date

2021-03-01, 1399/12/11

Ethics committee reference number

IR.BUMS.REC.1399.522

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**

The amount of pain in the knee joints

Timepoint

Visual analog scale score measurement at the beginning of the study and 6 weeks later

Method of measurement

visual analog scale

2**Description**

Western Ontario and McMaster Universities Osteoarthritis Index(WOMAC)

Timepoint

WOMAC score set at the beginning of the study and 6 weeks later

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index questionnaire (WOMAC)

Secondary outcomes**1****Description**

Pain intensity score

Timepoint

Pain intensity measurement at the beginning of the study and 6 weeks later

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index(WOMAC)

2**Description**

Intensity of joint stiffness

Timepoint

Measurement of joint stiffness at the beginning of the study and 6 weeks later

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index(WOMAC)

3**Description**

Ability to perform daily activities score

Timepoint

Scoring the ability to perform daily activities at the beginning of the study and 6 weeks later

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index(WOMAC)

Intervention groups**1****Description**

Intervention group: Injection of hyaluronic acid into the knee joint. Hyaluronic acid will be high molecular weight and will be injected once. The hyaluronic acid used will be of Iranian type and with Viscor brand from Nitka company. All injections will be performed by a physician to reduce any discrepancies in the type of injection to zero .

Category

Treatment - Drugs

2**Description**

Control group: Intra-knee corticosteroid injection. The glucocorticoid used to treat these people is triamcinolone acetone, which is FDA approved. In this group, 1 injection of corticosteroids in the amount of 1ml and 40mg is performed. The corticosteroid used is of the Iranian type and will be from Exir Company.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Birjand Emam reza hospital

Full name of responsible person

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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
Birjand 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
All data is potentially shareable after unidentified individuals
When the data will become available and for how long
Access period starts 3 months after the results are published
To whom data/document is available
Study data will be available to researchers working in academia and in industry, and who can apply for it.
Under which criteria data/document could be used
The use of documents in articles and industry and medical applications will be allowed. Analyzes on data

are also allowed.

From where data/document is obtainable

To receive the required documents and data, you can send your request via the following e-mail:

nn.mahdy10@gmail.com alireza.ghoreighi@bums.ac.ir

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

After submitting the application in the announced manner and stating the reason for the request, the applicant must wait for the researcher to respond and obtain permission from the sponsoring body, after which, if agreed, the documents and data will be sent to him.

Comments