

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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)

##### Phone

+98 56 3239 5000

##### Email address

alireza.ghoreishi@bums.ac.ir

##### 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

**Age**

From **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

**Province**

South Khorasan

**Postal code**

9717803077

**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 acetonide, 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**

Seyed Alireza ghoreishi

**Street address**

Taleghani blvd, Emam reza hospital

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3222 2600

**Email**

alireza.ghoreishi@bums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr. Toobi Kazemi

**Street address**

Ghaffari St. Birjand University of Medical Sciences

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3238 1200

**Email**

drtooba.kazemi@gmail.com

**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**

Birjand University of Medical Sciences

**Full name of responsible person**

Seyed Alireza ghoreishi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

**Street address**

Ghaffari St., Birjand University of Medical Sciences

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

098 56 32395000

**Email**

alireza.ghoreishi@bums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Seyed Alireza ghoreishi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

**Street address**

Ghaffari St., Birjand University of Medical Sciences

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3239 5000

**Email**

alireza.ghoreishi@bums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Seyed Alireza ghoreishi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

**Street address**

Ghaffari St., Birjand University of Medical Sciences

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

098 56 32395000

**Email**

alireza.ghoreishi@bums.ac.ir

**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**