

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effects of ultrasound-guided corticosteroid injection compared to mesenchymal stem cell injection in patients with knee osteoarthritis: a randomized controlled trial

#### Protocol summary

##### Study aim

The aim: compare the effect of ultrasound guided corticosteroid injection with mesenchymal stem cell injection in patients with osteoarthritis of the knee

##### Design

random sampling; convenience sampling and then patients will be assigned to two groups by block randomization. the study is double blind (patient and analyzed) Sample size: 30

##### Settings and conduct

patients with knee osteoarthritis referred to physical medicine clinics (Iran University of Medical Sciences). Patients are randomly divided into two groups in closed packaging

##### Participants/Inclusion and exclusion criteria

The main inclusion criteria: patients with mild to moderate OA of the knee (Kellgren Lawrence grade I, II and III); the absence of any acute or chronic infection; no history of any intra articular injection of the knee in three months ago; the absence of inflammatory articular diseases The main exclusion criteria: the willingness of patients to exit from the study.

##### Intervention groups

in initial time, 1 cc lidocaine 2% will be used for local anesthesia (skin) in both groups. then under sterile conditions, in one group 40 mg triamcinolone (1 cc) will be injected into the knee joint ( under ultrasound guided in suprapatellar Pouch). in another group under sterile conditions, 30 ×(8)10 mesenchymal stem cell with fat source under ultrasound guided (in suprapatellar pouch), will be injected into the joint.

##### Main outcome variables

Outcomes: before injection , pain intensity (VAS) , WOMAC score, clinical assessment (range of motion),maximum depth cartilage of distal femor joint surface in both groups will be determined and then this criteria evaluated at two weeks, one month and six

months post injection. the results will be compared before and after injection in each group and between the two group

#### General information

##### Reason for update

The start date of patient recruitment in the research should be changed to one month after the date of approval and receipt of the IRCT code. Research approval date: 2019-01-05 The registered date for admission is 10-23-2018, which I would like to change to 02-05-2019.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151017024572N19**  
Registration date: **2019-01-05, 1397/10/15**  
Registration timing: **prospective**

Last update: **2024-04-19, 1403/01/31**

Update count: **2**

##### Registration date

2019-01-05, 1397/10/15

##### Registrant information

###### Name

Arash Babaei-Ghazani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

babaei-ghazani.a@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2019-02-05, 1397/11/16

**Expected recruitment end date**

2020-02-05, 1398/11/16

**Actual recruitment start date**

2019-02-05, 1397/11/16

**Actual recruitment end date**

2020-05-05, 1399/02/16

**Trial completion date**

2020-05-05, 1399/02/16

**Scientific title**

The effects of ultrasound-guided corticosteroid injection compared to mesenchymal stem cell injection in patients with knee osteoarthritis: a randomized controlled trial

**Public title**

Effect of mesenchymal stem cell in knee osteoarthritis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with mild to moderate OA of the knee (Kellgren Lawrence grade I, II and III) Knee pain for at least six months Age 18 to 75 years old The absence of any acute or chronic infection No pregnancy or lack of planning to get pregnant No history of any intra articular knee injection in three months ago The absence of inflammatory articular disease or secondary osteoarthritis No history of knee surgery No severe underlying disease such as uncontrolled diabetes, Use of anticoagulants Lack of daily use of opioid and non opioid analgesics

**Exclusion criteria:**

The willingness of patients to exit from the study at any stage of the study

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **30**

Actual sample size reached: **27**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random assignment to intervention and control groups

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients are randomly divided into two groups in closed packaging

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Block randomization

**Secondary Ids**

empty

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

committee of Iran University of Medical Sciences Street address Iran University of Medical Sciences,

**Street address**

Iran University of Medical Sciences, Hemmat Highway, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2018-08-26, 1397/06/04

**Ethics committee reference number**

IR.IUMS.REC.1397.370

**Health conditions studied****1****Description of health condition studied**

Primary knee osteoarthritis, bilateral

**ICD-10 code**

M17.0

**ICD-10 code description**

Primary knee osteoarthritis, bilateral

**Primary outcomes****1****Description**

The severity of pain

**Timepoint**

Zero, two weeks, one and six months after

**Method of measurement**

Visual Analog Scale(VAS)

**2****Description**

The severity of symptoms and functional limitations

**Timepoint**

Zero, two weeks, one and six months after

**Method of measurement**

By using WOMAC questionnaire

**3****Description**

Range of motion

**Timepoint**

Zero, two weeks, one and six months after

**Method of measurement**

Goniometer

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

Side effects

**Timepoint**

two and four weeks after

**Method of measurement**

Physical examination

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

Intervention group: mesenchymal stem cell injection will be performed under the ultrasound guid in the knee joint which will be done by an experienced physical medicine and rehabilitation specialist; using supra patellar approach.

**Category**

Treatment - Other

**2****Description**

Control group: corticosteroid injection will be performed under the ultrasound guid in the knee joint which will be done by an experienced physical medicine and rehabilitation specialist; using supra patellar approach.

**Category**

Treatment - Other

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

Firuzgar hospital

**Full name of responsible person**

Khatereh Abdolmaleki/Masume Zoghali

**Street address**

Valadi Ave.,Valie asr Blvd.,Tehran Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1593747811

**Phone**

+98 21 4128 9221

**Email**

khatereh.abd@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyed Kazem Malakoti

**Street address**

Iran University of Medical Sciences, near Milad tower, Hemmat

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۱۴۴۹۶۱۴۵۳۵

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PR@iums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Khatereh Abdolmaleki

**Position**

Resident of Physical medicin and rehabilitation

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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

Iran University of Medical Sciences

**Full name of responsible person**

Dr.Arash Babaei

**Position**

Associate professor of physical medicine and rehabilitation

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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

Iran University of Medical Sciences

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**Position**

Resident of Physical medicine and rehabilitation

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Medical doctor

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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**

Prevention from scientific theft

**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**

No - There is not 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