Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of ultrasound-guided corticosteroid injection compared to mesenchimal 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 mesenchimal 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 mesenchimal 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
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Iran (Islamic Republic of)
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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 mesenchimal stem cell injection in patients with knee osteoarthritis: a randomized controlled trial

Public title
Effect of mesenchimal 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 SciencesStreet 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 osteoarthrosis, bilateral
ICD-10 code
M17.0
ICD-10 code description
Primary knee osteoarthrosis, 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 questionnare

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: mesenchimal 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
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1593747811
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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
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Person responsible for scientific inquiries

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Associate professor of physical medicine and rehabilitation
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Person responsible for updating data

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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